A STUDY TO COMPARE THE EFFECTIVENESS OF ORAL HONEY APPLICATION AND CHLORHEXIDINE MOUTH WASH IN HEALING ORAL MUCOSITIS DUE TO CHEMO AND RADIATION AMONG CANCER PATIENTS IN A SELECTED HOSPITAL AT KANYAKUMARI DISTRICT

DISSERTATION SUBMITTED TO

THE TAMILNADU DR. M.G.R. MEDICAL UNIVERSITYCHENNAI

IN PARTIAL FULFILLMENT OF REQUIREMENT FOR THE AWARD OF DEGREE OFMASTER OF SCIENCE IN NURSING

OCTOBER- 2014

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OCTOBER- 2014

CERTIFICATE

This is to certify that the dissertation entitled,**"A study to compare the effects of oral honey application and chlorhexidine mouth wash in healing oral mucositis among cancer patients due to chemo and radiation in the selected hospital at Kanyakumari district"** is a bonafide work done byMr.M.Berlin Rajan, II M.Sc (N), Global College of Nursing, Nattalam in partial fulfillment of the University rules and regulations for the award of M.Sc (N) degree under my guidance and supervision during the academic year October 2012-2014.

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ABSTRACT

“The most important thing in illness is never to lose heart”

-Nikolai Lenin

Introduction:

Most patients with cancer experience oral mucositis during chemotherapy and radiation therapy. Ignoring this oral mucositis can contribute to worsening overall health of patients and slowed recovery process.

Objectives of the Study

1) To assess the level of oral mucositis due to chemo /radiation therapy in patient with cancer among Groups 1 and 2.
2) To assess the post test level of oral mucositis after oral application of honey for group 1 and chlorhexidine mouth wash for group 2.
3) To assess the effect of oral honey application in healing oral mucositis due to chemo/radiation by comparing the pre and post test scores within group 1.
4) To assess the effect of chlorhexidine mouth wash in healing oral mucositis due to chemo/radiation by comparing the pre and post test scores within group 1.
5) To compare the effects of oral honey application and chlorhexidine mouth wash in healing oral mucositis due to chemo/radiation

6) To determine the association between the pretest level of oral mucositis due to chemo/radiation among groups 1 and 2 and their selected demographic variables such as age, gender, frequency of mouth wash, personal habits, duration of illness, stages of cancer, received chemotherapy, received radiation therapy

The investigator adopted General System Theory as the conceptual framework for the study. Quasi experimental with time series pre testpost test design was used and the formal consent was obtained from International Cancer Center, Neyyoor and the investigator selected 60 samples using purposive sampling technique and who are fulfilling the inclusive criteria were selected as a samples both in group 1 and group 2.

Descriptive and inferential statistics were used to analyze the data. Analysis of demographic variables was done in terms of frequency and percentage distribution. Comparison of post test level of oral mucositis between the group 1 and group 2 was analysedby 't' test. Which is an inferential statistical analysis. Association of post test level of oral mucositis in the group 1 and group 2 with demographic variables was analysed by using chi-square test.

The findings concluded that in the group 1, 17(57%) of them had Grade 3 level oral mucositis, 13(43%) had Grade 4 level of oral mucositis in their pre-test assessment. Whereas in the post-test 20(67%) of them had Grade 0, 10(33%) had Grade 1 level of oral mucositis.

The findings concluded that in the group 2, 20(67%) of them had Grade 3 level oral mucositis, 10(33%) had Grade 4 level of oral mucositis in their pre-test assessment. Whereas in the post-test 11(37%) of them had Grade 0, 19(63%) had Grade 1 level of oral mucositis.

It revealed that among group 1 the mean pre-test score was 3.5 with standard deviation with 0.489. The mean post-test was 0.3 with standard deviation 0.447. The mean difference was 3.2. The obtained ‘t’ value was 2.68, where as the table value was 2.04. It was significant at $p< 0.05$ level.

It revealed that among group 2 the mean pre-test score was 3.6 with standard deviation with 0.465. The mean post-test was 0.6 with standard deviation 0.474. The mean difference was 3.0. The obtained ‘t’ value was 2.65, where as the table value was 2.04. It was significant at $p< 0.05$ level.

Hence it was inferred that the oral honey application and chlorhexidine mouth wash was equally effective in healing oral mucositis among clients with cancer.

TABLE OF CONTENTS

CHAPTER	CONTENTS	PAGE NO
I	**INTRODUCTION**	**1-11**
	Need for the Study	5-8
	Statement of the Problem	8
	Objectives of the Study	8-9
	Hypotheses	9
	Assumptions	9-10
	Delimitations of the study	10
	Operational definition	10-11
	Conceptual framework	12-14
II	**REVIEW OF LITERATURE**	**15-32**
	• *Studies related to incidence of oral mucositis due to chemo and radiation therapy in cancer patients.*	15-19
	• *Studies related to healing of chemo radiation related oral mucositis with honey application*	19-29
	• *Studies related to healing of chemo radiation related oral mucositis with chlorhexidine mouth wash*	29-30
	• *Studies related to comparison of effects of other medications and chlorhexidine mouth wash in healing chemo radiation related oral mucositis*	30-32
III	**METHODOLOGY**	**33**
	Research Approach	34
	Research Design	34-35
	Variables identified	36

CHAPTER	CONTENTS	PAGE NO
	Setting of the Study	36-37
	Population	37
	Sample	37
	Sampling Technique	37-38
	Sampling Criteria	38
	• *Inclusion Criteria*	
	• *Exclusion Criteria*	
	Description of the Tool	39-40
	Content Validity	40
	Reliability	40
	Ethical consideration	40-41
	Pilot Study	41-42
	Data Collection Procedure	42
	Plan for data analysis	43
IV	**DATA ANALYSIS AND INTERPRETATION**	**44-71**
V	**DISCUSSION**	**72-81**
VI	**SUMMARY,CONCLUSION AND RECOMMENDATIONS**	**82-88**
	BIBLIOGRAPHY	**89-92**
	APPENDICES	**i-v**

LIST OF TABLES

TABLE No.	TITLE	PAGE No.
1.1	Frequency and Percentage Distribution of demographic variables in the group 1 and group 2.	46-47
2.1	Frequency, percentage distribution of selected subjects as per their level of oral mucositis in group 1	58
2.2	Frequency, percentage distribution of selected subjects as per their level of oral mucositis in group 2	59
3.1	Comparison of pre and post test level of oral mucositis among patient with cancer in group 1	60
3.2	Comparison of pre and post test level of oral mucositis among patient with cancer in group 2	62
3.3	Comparison of post and post test level of oral mucositis among patient with cancer in group 1 and 2	64
4.1	Association value of pre test level of oral mucositis with selected subjects in group 1 and 2	66-68

LIST OF FIGURES

FIGURE NO.	FIGURES	PAGE NO.
1.1	Conceptual Framework- based on General System Theory(Ludwig von Bertalanffy)	14
2.1	The schematic diagram of representing of Research Methodology	33
3.1	Bar diagram depicting the percentage distribution of samples according to age in years in the group 1 and group 2	50
3.2	Bar diagram depicting the percentage distribution of samples according to gender in years in the group 1 and group 2	51
3.3	Bar diagram depicting the percentage distribution of samples according to frequency of mouth wash in the group 1 and group 2	52
3.4	Bar diagram depicting the percentage distribution of samples according to personal habits in the group 1 and group 2	53
3.5	Bar diagram depicting the percentage distribution of samples according to stages of cancer in the group 1 and group 2	54
3.6	Bar diagram depicting the percentage distribution of samples according to received chemotherapy in the group 1 and group 2	55
3.7	Bar diagram depicting the percentage distribution of samples according to received radiation therapy in the group 1 and group 2	56
3.8	Bar diagram depicting the percentage distribution of samples according to duration of illness in the group 1 and group2	57

FIGURE NO.	FIGURES	PAGE NO.
3.9	Bar diagram depicting the comparison of pre and post test level of oral mucositis among patient with cancer in group 1	61
3.10	Bar diagram depicting the comparison of pre and post test level of oral mucositis among patient with cancer in group 2	63
3.11	Bar diagram depicting the Comparison of post and post test level of oral mucositis among patient with cancer in group 1 and 2	65

LIST OF APPENDICES

APPENDIX NO	TITLE	PAGE NO
I	Letter Seeking and Granting Permission to Conduct Study	i
II	Tool for data collection	ii-iv
	• Section A- Demographic variables	ii
	• Section B- WHO Oral Toxicity Scale	iv
	• Section C- Intervention	v

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ABSTRACT

CHAPTER -I

INTRODUCTION

CONCEPTUAL FRAMEWORK

CHAPTER -II

REVIEW OF LITERATURE

CHAPTER -III

METHODOLOGY

CHAPTER -IV

DATA ANALYSIS AND INTERPRETATION

CHAPTER -V

DISCUSSION

CHAPTER –VI

SUMMARY, CONCLUSION, IMPLICATION

AND

RECOMMENDATIONS

BIBLIOGRAPHY

APPENDICES

CHAPTER I

INTRODUCTION

"**Life is not measured by the breaths we take, but rather by the moments that take our breath away."**

-Hilary Cooper

There are over 20 million people living with cancer in the world today. The estimate number of cases each year is expected to increase from 2 million in 2000 to 15 million in 2020. The number of cancer deaths annually will increase from about 6 million to l0 million. Cancer has now become the third leading cause of deaths in Asian countries. In India, there are approximately 2.2 million cases of cancer and around 7,00,000 new cases are being detected each year.Among Indian women cancer in the breast account for nearly 60 percent of all cancers. Several studies reported that head and neck cancer is proportionately on the increase in a metropolitan area of India.

Cancer, as a malignant neoplasm, is a broad group of various diseases, all involving unregulated cell growth. In cancer, cells divide and grow uncontrollably, forming malignant tumours, and invade nearby parts of the body. The cancer may also spread to more distant parts of the body through the lymphatic system or bloodstream. Not all tumours are cancerous. There are over 200 different known cancers that afflict humans.

Cancer is one of the leading causes of death around the world. It is estimated that around 84 million people died of cancer between 2005 and

2015 without intervention. Low income and medium income countries are harder hit by cancer than the developed countries. It is essential to address the world's growing cancer burden and effective control measures to minimise the risk.

The worldwide cancer incidence rate is estimated as seven million with the annual mortality of about five millions. It is projected, by the year 2015, nearly 2/3 of all cancer causes severe life threatening problems in the developing countries alone. Cancer is estimated to account for almost 6% of the entire global burden of the disease.

Chemotherapy and radiation therapy are the most widely used interventions for the treatment of cancer. Although these treatments are employed to improve the patient's quality of life, they are associated with several side effects. Annually, there are approximately 400,000 cases of treatment-induced damage to the oral cavity. Children and adolescents make up a unique group of patients in a cancer setting and are at increased risk of oral mucositis.

Cancer patients undergoing chemotherapy usually become symptomatic four to five days after beginning treatment, reaching a peak at around day 10, and then slowly improving over the course of a few weeks. Mucositis associated with radiotherapy usually appears at the end of the second week of treatment and may last for six to eight weeks. As a result of cell death in reaction to chemo- or radio-therapy, the mucosal lining of the mouth becomes thin, may slough off and then become red, inflamed and

ulcerated. The ulcers may become covered by a yellowish white fibrin clot called a pseudo membrane.

Chemotherapy is the specific treatment of cancer, where the specific antineoplastic agents are used. These agents interfere with the cellular function, including replication. It is used primarily to treat the systemic disease. It may be combined with surgery, radiation therapy, or both. Repeated dose of chemotherapy are necessary over a prolonged period.

The concept of perfect positive health cannot become a reality because man will never be so perfectly adapted to his environment that his life will not involve struggles; failures and sufferings. Positive health will therefore, always remain mirages, because everything in our life is subject to change .Health in this context has been described as a potentiality - the ability of an individual to modify him or itself continually in the face of changing conditions of life.

Interest in complementary alternative medicine has grown dramatically over the past several years. According to survey results 80% of patients repeated using some type of complementary alternative medicine, in that 54 % took herbal products and 30 % used relaxation techniques.

Direct Mucositis - The epithelial cells of the oral mucosa undergo rapid turnover, usually every 7 to 14 days, which makes these cells susceptible to the effects of cytotoxic therapy. Both chemotherapy and radiation therapy can interfere with the maturity and cellular growth of epithelial cells, causing changes to normal turnover and cell death.

Indirect Mucositis - Oral mucositis can also be caused by the indirect invasion of gram-negative bacteria and fungal species. Patients are at increased risk for oral infections when they are neutropenic, and this usually happens when indirect stomatotoxicity appears. The onset of mucositis secondary to myelo suppression varies, depending upon the timing of the neutrophil count associated with the chemotherapy agent administered, but typically develops anywhere from 10 to 21 days after chemotherapy administration.

Oral mucositis is a painful inflammation and ulceration of mucous membranes of the oral cavity. It is a common side effect of most chemotherapeutic drugs, and radiotherapy of the oral, and head and neck cancers. In addition to impacting the quality of life of cancer patients, it influences treatment decisions, often requiring reductions of dose and delays or even discontinuation of therapy resulting in tumor rebound and cancer relapse. Mucositis-related ulcers are also prone to infections, which may be life-threatening and may exacerbate underlying oral, gum, dental, andperiodontal problems. Oral mucositis is a debilitating complication commonly seen in 25% to 33% of cancer patients treated with chemotherapy; and nearly 100% in those Treated with high-dose myeloablative chemotherapy before undergoing bone marrow transplantation (BMT).

NEED FOR THE STUDY

Districts in the central, south, northeast India have the world's highest incidence of cancer associated with tobacco in India. Aizawl district in the northeast state of Mizoram has the world's highest incidence of lower pharynx cancer (11.5 per 1,00,000 people) and tongue cancer (7.6 per 1,00,000 people) in men and also highest in stomach cancer wardha, Madhya Pradesh has the highest incidence of mouth ulcer in the world. Rate of stomach cancer were high among men in Bangalore, Chennai and also detected highest incidence in women in coastal district, Kerala, Karnataka and Goa. Lung cancer is the most common cancer in men in Calcutta, Mumbai and New Delhi.

(Population Based Cancer Registries, 2001)

The results of two clinical trials evaluating palifermin for reducing theseverity of oral mucositis in patients undergoing chemo andradiotherapy for head and neck cancer were published in 2011. The results of those trials are encouraging, as both studies were well-designed randomized controlled trials. Both trials evaluated whether the use of palifermin can reduce the frequency and severity of grade 3 and grade4 oral mucositis (as defined by World Health Organization criteria) in patients receiving cisplatin plus concurrent radiotherapy for head and neck cancer. The two trials each enrolled almost 190 patients (just under 95 patients per treatment or placebo group), which provided enough power (≥90%) to detect a reduction of 25% in the combined rate of grade 3 and grade 4 oral mucositis with a two-sided

alpha value of 5%. The primary endpoint in both studies was the cumulative frequency of grade 3 and grade 4 oral mucositis. Secondary endpoints included the duration and time to onset of mucositis, opioid analgesic use (cumulative dose), and the frequency of chemotherapy treatment delays and radiotherapy. (Edward Li, James A, 2012)

Prevalence rate of oral mucositis in cancer patients have been estimated up to 40% in patients receiving standard dose chemotherapy, 90% in head and neck cancer patients subjected to chemo-radiotherapy and 90% in patients undergoing high dose myeloablative chemotherapy for hematopoietic stem cell transplant. Oral mucositis is a complex process of biologic phenomena primarily related to the type and dosage of cancer therapy, oral mucositis is usually observed three to five days after initiation of chemotherapy. Chemotherapy induced oral mucositis reaches peak intensity at 7-14 days and slowly resolves unless complicated by infection or repeated drug administration.

Studies have shown that an oral care protocol (tooth brushing, chlorhexidine rinse [0.2%], and saline) resulted in a 38% reduction in incidence and a significant reduction in severity and associated oral pain in pediatric patients with cancer. Ice chipsor saline mouth rinse may lessen the severity or help prevent symptoms of mucositis or mouth sores in patients receiving melphalan and autologous stem cell transplant for multiple myeloma. It is not yet known whether ice chips are more effective than saline mouth rinse in reducing or preventing mucositis.

Oral mucositis is a significant problem in patients undergoingchemotherapeutic management for solid tumors. In one study it was reported that 303 of 599 patient (50%) receiving chemotherapy for solid tumor or lymphoma developed oral mucositis or GI mucositis in 22% of 1236 cycles of chemotherapy. GI mucositis in 7% of cycles. An even higher percentage (approximately 75-80%) of patient who receive high dose chemotherapy prior of hemopoietic cell transplantation develop clinically significant oral mucositis. (Rajesh. V. Lalla, 2008).

Dry mouth and distorted taste were reported by 63 (72%) and 55 (63%)subjects separately. The 55% and 40% subject reported having weight loss and dysphagia respectively. The mean intensity and the distress score of oral mucositis and oral dysfunction reported by the subjects ranged from 1.96 to 2.51 and 1.58 to 1.09 respectively. (Shatin, 2007).

This comparative study is carried out on a sample of 15 non-smoking patients with chronic periodontitis at the Department of Periodontology, the International University of Catalunya, Barcelona, Spain. All patients used either 0.2% chlorhexidine Mouthwash (control group =bottle B) or chlorhexidine with ADS (test group=bottle A) For 15 days. Each patient first rinsed with a randomly assigned mouthwash for 15 days followed by a 15-day washout period. Subsequently, each patient used a second mouthwash. Before each cycle, a full dental prophylaxis was performed. The plaque, gingival, and Brecx staining indexes were used,The result showed less tooth staining with test group ($P<0.01$). No statistically

significant differences were observed in plaque (P =0.1496) and gingival indexes(P =0.1688). Eighty-eight percent of patients followed the instructions outlined in the protocol. In terms of other adverse effects, two patients reported a bad taste with both mouthwashes**.**(Solis C, Santos A. 2011)

STATEMENT OF THE PROBLEM

A study to compare the effects of oral honey application and chlorhexidinemouth wash in healing of oral mucositis due to chemo and radiation among cancer patients in the selected hospital at Kanyakumari district.

OBJECTIVES

1. To assess the level of oral mucositis due to chemo /radiation therapy in patient with cancer among Groups 1 and 2.
2. To assess the post test level of oral mucositis after oral application of honey for group 1 and chlorhexidine mouth wash for group 2.
3. To assess the effect of oral honey application in healing oral mucositis due to chemo/radiation by comparing the pre and post test scores within group 1.
4. To assess the effect of chlorhexidine mouth wash in healing oral mucositis due to chemo/radiation by comparing the pre and post test scores within group 1.

5. To compare the effects of oral honey application and chlorhexidine mouth wash in healing oral mucositis due to chemo/radiation
6. To determine the association between the pretest level of oral mucositis due to chemo/radiation among groups 1 and 2 and their selected demographic variables such as age, gender, frequency of mouth wash, personal habits, duration of illness, stages of cancer, received chemotherapy, received radiation therapy.

HYPOTHESES:

The following hypotheses are formulated for the study and were tested at 0.05 level of significance.

H_1: There is a significant difference between pre and post test levels of oral mucositis. In group 1 and 2

H_2: There is a significant difference between the post tests levels of oral mucositis.Among the group 1 and 2.

H_3: There is a significant association of the pre tests levels of oral mucositis in group1and 2 With the selected demographic variables such as age, gender, frequency of mouth wash, personal habits, duration of illness, stages of cancer, received chemotherapy, received radiation therapy.

ASSUMPTIONS

1. All the cancer patients receiving chemo and radiation therapy may develop oral mucositis as side effects.

2. Honey application and chlorhexidine mouth wash may have positive effects of healing oral mucositis due to chemo/radiation.
3. Oral honey application and chlorhexidine mouth wash may differ in their. Healing effects on oral mucositis due to chemo/radiation.

DELIMITATION OF THE STUDY:

This study was delimited to

- Only 60 samples
- Only one hospital (oncology)
- Only 4 weaks for data collection
- Only cancer patients on chemo/radiation therapy
- Only patients with cancer at 2^{nd} ,3^{rd}, or 4^{th} stage
- Only cancer patients receiving chemo/Radiation from 2^{nd} cycle

OPERATIONAL DEFINITION

1.EFFECTS

In this study effect refers to the positive outcome of honey application in oral cavity and chlorhexidine mouth wash in complete healing of oral mucositis among cancer patients.

2.ORAL HONEY APPLICATION

In this study it refers to introducing 5 ml of pure honey into the oral cavity and asking the client to hold it for 30 seconds until it spread over and then to swallow it, thus it is done four times a day for four days.

3.CHLORHEXIDINE MOUTH WASH

In this study refers to rinsing mouth and oral cavity with 10 ml of0.2% chlorhexidine solution for 30 seconds for four times a day for four days.

4.HEALING

In this study it refers to complete disappearance of the infected cells or mucous layer in the oral cavity especially on the tongue.

5.ORAL MUCOSITIS

In this study it refers to inflammation of the cells coating the oral cavity and tongue producing whitish or reddish patches and sores over the tongue and oral cavity causing pain, swallowing, swallowing and speech difficulty and loss of appetite.

6.CANCER PATIENTS

In this study cancer patient refers to the person diagnosed to have 2^{nd} or 3^{rd} or 4^{th} stage of a disease with abnormal proliferation of cells in any body organ or in blood.

7.CHEMO AND RADIATION THERAPY

In this study it refers to a kind of therapeutic measure done for have 2^{nd} or 3^{rd} or 4^{th} stage of cancer in which certain cancer cells killing drugs are given to and anticancer rays are passed to the affected areas of such patients.

CONCEPTUAL FRAMEWORK

GENERAL SYSTEM THEORY (LUDWIG VON BETTENLAFFY-1968)

Tabot (1995) defined conceptual framework a network of interrelated changes that provide a structure for organizing and describing the framework that facilitates visualizing the problem and places the variables in the logical manner.

All system is open in that there is a continual exchange of matter, energy and intervention. There are three components;

- Input
- Throughput
- Output

Input

The information that enters into the system from the environment through its boundaries.

In this study input is the pre assessment on level of oral mucositis by using WHO Oral Toxicity Scale among groups 1 and 2 and their demographic variables that could have indirectly contributed to the problem.

Throughput

Is the operation phase ie, it is the process that allows the input to be changed as output in such a way that it can be readily used by the system.

In this study during the activity phase the investigator administered oral honey application to group 1 introducing 5 ml of pure honey into the oral cavity and asking the client to hold it for 30 seconds until it spreads over and then swallowing it, thus it is done four times a day for four days and to group 2 chlorhexidine mouth wash was done by rinsing mouth and oral cavity with 10 ml of 0.2% chlorhexidine solution for 30 seconds for four times a day for four days.

Output

Post test was done with the same scale among both the groups and was detected using same WHO Oral Toxicity Scale.

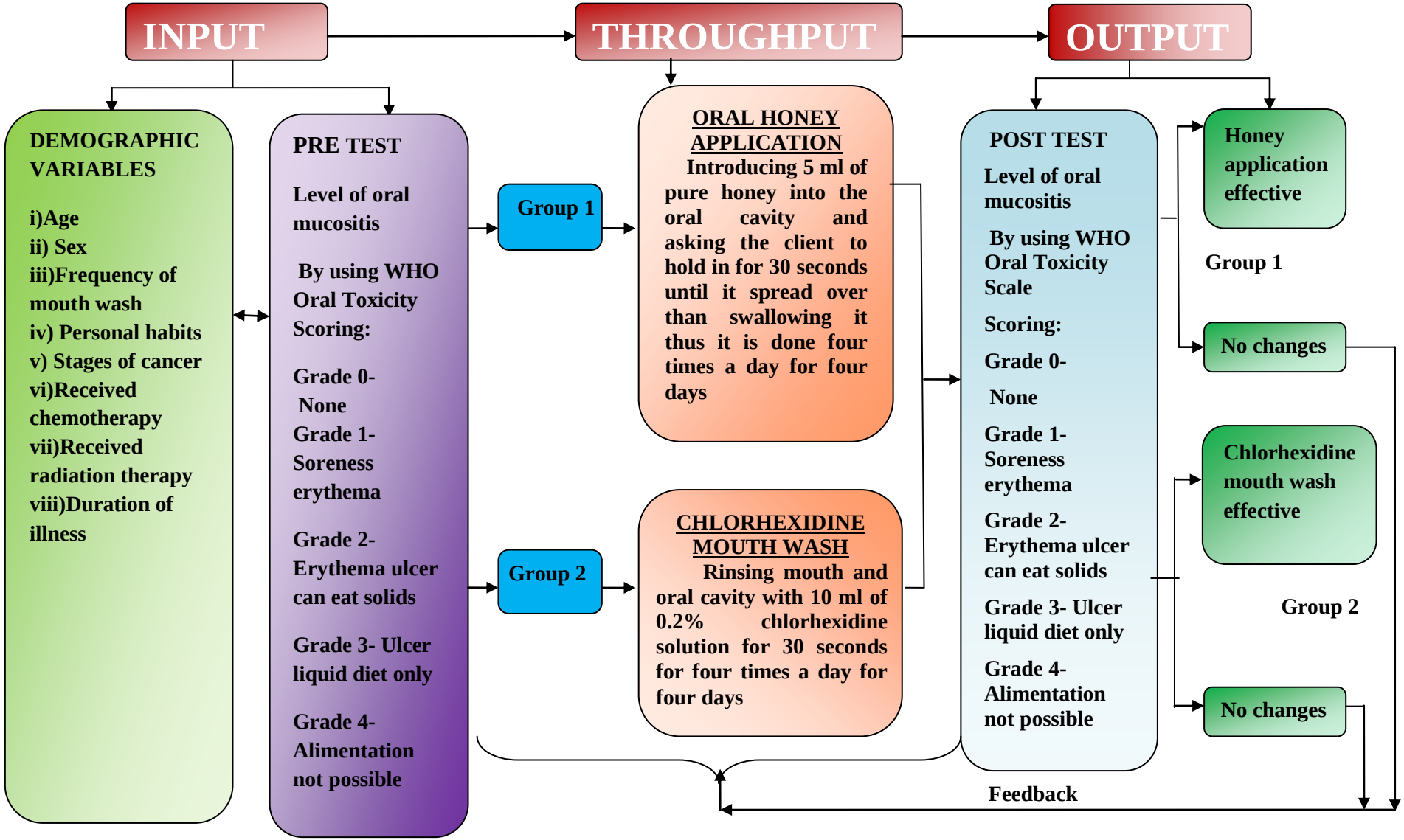
Feedback

It emphasis to strengthen the input and throughput and it was necessary if the output show no reduction in level of oral mucositis in the both groups.

In this study, the post tests level of oral mucositis was found to be significantly reduced among both the groups and a difference was shown between the post tests level of oral mucositis and hence feedback was not necessitated.

FIGURE 1.1

Conceptual frame work based on Modified General System Theory (Ludwig von Bertalanffy – 1968)



CHAPTER II

REVIEW OF LITERATURE

The literature review involves the systematic identification, location, scrutiny and summary of written materials that contain information of a research problem **(Polit and Hungler 2004).**

A review of literature is a key step in research process and it refers to extensive, exhaustive and systemic examination of publications relevant to research project. The researcher presents the review of literature for the present study under the following headings.

1. Studies related to incidence of oral mucositis due to chemo and Radiation therapies in cancer patients
2. Studies related to healing of chemo and radiation related oral Mucositis with honey application.
3. Studies related to healing of chemo/radiation related oral mucositis With chlorhexidine mouth wash.
4. Studies related to comparison of effects of other medications and Chlorhexidine mouth wash in healing chemo/radiation related oral mucositis

1. Studies related to incidence of oral mucositis due to chemo and Radiation therapies in cancer patients.

Oral mucositis is a common and significant problem of cancer chemotherapy, especially patients who receives high-dose therapy. Two

recently published retrospective analyses of patient complaints following chemotherapy have identified oral mucositis as the worst toxicity reported by patients, and what is more important is that patients indicated that oncology healthcare team members do a poor job of managing and providing methods of symptom relief. Twenty percent of patients surveyed indicated that they received no symptom relief at all **(Ronald., 2005).**

A prospective observational study was conducted to examine the burden of mucositis and risk of complications in head and neck cancer patients receiving radiation with or without chemotherapy. Oral mucositis was assessed at the end of two, four and six weeks by using questionnaire for head and neck cancer. A 12 team instrument was used to measure mouth and throat soreness and pain and limitation in oral functions. Data were collected at every week and results showed that oral mucositis had initially developed for who with radiation therapy and severe mucositis and throat soreness occurred in 76 percent of patients **(Bjarnason, G.,2005).**

A descriptive study was conducted to find out the incidence of oral mucositis in cancer treatment. Patients receiving radiation therapy and chemotherapy were included in the study. Patients oral cavity was assessed weekly and identified that patients receiving chemotherapy oral mucositis usually develop from 10 to 12 days of administration and in radiation therapy mucositis occurred after 7 to 10 days of administration, the incidence and severity was high in patients receiving both **(Verdi. C.,2005).**

A study was conductd to explore the relationship between oral mucositis and selected clinical and economic outcomes of patients with radiation and chemotherapy. Subjects who participated in this study consisted of 92 patients from eight centers. Oral mucositis scoring system (Oral Mucositis Assessment Scale) was used to assess oral mucositis and examined the relationship between patients peak oral mucositis scores and days with fever, the occurrence of infection, days of total parenteral nutrition (TPN), and days of injectable narcotic therapy, days in hospital, total hospital charges for the index admission, and vital status at 100 days. Results showed that Patients' peak oral mucositis scores reached the full range of possible values (0 to 5) and were significantly ($P<0.05$) correlated with all of the outcomes and it revealed that oral mucositis is associated with significantly worse clinical and economic outcomes in cancer treatment**.(Fayed, L.,2004).**

Parulekar et al.have estimated that chemotherapy-induced mucositis varies from 40 to 76% in patients treated respectively with standard and high-dose chemotherapy. Nearly all (90% to 97%9,24) patients receiving radiotherapy in the head and neck will develop some degree of mucositis. Of these patients treated with radiotherapy with or without chemotherapy, 34% to 43% presented with severe mucositis. As a result, the patients quality of life got affected, hospital admission rates are higher, the use of total parenteral nutrition is increased and interruption of treatment was more frequent, all of which compromise tumor control.

Mucositis causes 9% to 19% of chemotherapy and radiotherapy interruption.

According to **Andy Trotti et al**the study protocol, databases were searched for randomized clinical trials (English only, 1996–1999) of patients with head and neck cancer receiving RT with or without chemotherapy that reported one or more outcomes of interest. Thirty-three studies (*n*=6181 patients) met inclusion criteria. Mucositis was defined using a variety of scoring systems. The mean incidence was 80%. Over one-half of patients (56%) who received altered fraction RT (RT-AF) experienced severe mucositis (grades 3–4) compared to 34% of patients who received conventional RT. Rates of hospitalization due to mucositis, reported in three studies (*n*=700), were 16% overall and 32% for RT-AF patients. 11% of patients had RT regimens interrupted or modified because of mucositis in five studies (*n*=1267) . Data insufficiency or heterogeneity prohibited analysis of mucositis severity and other associated outcomes, such as oral pain, dysphagia and opioid use.

Rubina C. M.(2012) did a study on evaluation of some oral post radiotherapy squeal in patients treated for head and neck tumors. One hundred patients (24 women, 76 men) ranging in age from 30 to 83 years (mean 59.2 years) were examined. Time since radiotherapy ranged from 1 to 72 months (mean 28 months). The total mean radiation dose received by the patient was 5, 955 CGY. The evaluation protocol included anamnesis, intraoral and extra oral examination, measurement of stimulated

salivary flow and salivary PH symptoms reported by the patients included dry mouth (68%), dysphagia (38%) and dysgeusia (30%). In 64% of the patient, the mean salivary flow rate was less than 0.7 ml/ min. the mean salivary PH was 6.97 (+/- o.714) stimulated salivary flow increased with increasing post radiotherapy time (P< 0.05). As a conclusion the prevalence of mucositis was associated with higher radiation doses (P< 0.05) and the prevalence of atrophic candiadiasis was related to a longer post treatment period (P < 0.05).

2.Studiesrelated to healing of chemo and radiation related oral Mucositis with honey application.

Rashad UM(2006) did a study on honey as topical prophylaxis against radio chemotherapy induced mucositis in head and neck cancer. The aim of the study is to evaluate the efficacy of pure natural honey as against radio chemotherapy induced mucositis. The study was done in Assiut university Hospital, Egypt between January 2005 and july 2006. 40 patients diagnosed with head and neck cancer were entered into the trial. Enrolled patients were randomized to either the treatment group, receiving concomitant chemotherapy and radiotherapy plus prior topical application of pure honey, or the control group, receiving concomitant chemotherapy and radiation therapy without honey. Patients were evaluated clinically every week to assess development of radiation mucositis. In the results in the treatment group, no patients developed grade four mecositis and only 3

patients (15%) developed grade three mucositis. In the control group 13 patients (65%) developed grade three or four mucositis ($p < 0.05$). As a conclusion this study shows that prophylactic use of pure natural honey was effective in reducing mucositis resulting from radio chemotherapy in patients with head and neck cancer.

Biswa Mohan Biswal (2003) did a study on topical application of honey in the management of radiation mucositis. The aim of the study was to evaluate the effect of pure honey on radiation induced mucositis. 40 patients diagnosed with head and neck cancer requiring radiation to the oropharyngeal mucosal area were divided into two groups to receive either radiation alone or radiation plus topical application of pure natural honey. Patients were treated using a 6 mv linear accelerator at a dose rate of 2 Gy per day five times a week up to a dose of 60 – 70 Gy. In this study patients were advised to take 20 ml of pure honey 15 min before, 15 min after and 6 hour post radiation therapy. Patients were evaluated every week for the development of radiation mucositis using the radiation therapy by oncology group (RTOG) grading system. The main result of the study was that there was significant reduction of symptomatic grade ¾ mucositis among honey – treated patients compared to controls. Ie, 20% vs 75% (p 0.00058). The compliance of honey treated group of patients was better than controls. As a conclusion topical application of natural honey is a simple and cost-effective treatment in radiation mucositis.

Apitherapy News (2008) the aim of the study was to evaluate the effect of pure natural honey on radiation induced mucositis. In this randomized single blind (examiner blind) clinical trial 40 patients with head and neck cancer requiring radiation to the oropharyngeal mucosa were randomly assigned to two groups. Twenty patients assigned to the study group received honey, while both the study and control groups received standard head and neck radiation therapy based on a standard protocol. In the study group patients were instructed to take 20 ml of honey 15 minutes before radiation therapy, then again at the interval of 15 minutes and six hours after radiation. In control group patients were instructed to rinse with 20 ml of saline before and after radiation. Patients were evaluated weekly for progression of mucositis using the oral mucositis assessing scale (OMAS). Result showed a significant reduction in mucositis among honey applied patients compared with control (p = o.ooo). As a conclusion with in the limits of this study the results showed the application of natural honey is effective in managing radiation induced mucositis.

S.M. AL- Gezawy (2008) did a study on honey as topical prophylaxis against radiotherapy- induced mucositis in head and neck cancer. The aim of the study was to evaluate the efficacy of pure honey as topical prophylaxis against radiotherapy- induced mucositis, and culturing of pathogenic oral and oropharyngeal microbes. The study was done in Assiut University Hospital, Egypt, between January 2005 and july 2006. Forty patients diagnosed with head and neck cancer were entered in to trial.

Enrolled patients were randomized to either the treatment group, receiving concomitant chemotherapy and radiotherapy plus prior topical application of pure natural honey, or the control group, receiving concomitant chemotherapy and radiotherapy without honey. patients were evaluated clinically every week to assess development of radiation mucositis. Aerobic cultures and candida colonization assessment were undertaken, via oral and oropharyngeal swabs, prior to and at the completion of irradiation, and when infection was evident. In the result in treatment group, no patients developed grade four mucositis and only three patients (15%) developed grade three mucositis where as in the control group, 13 patients, (65%) developed grade three to four mucositis (p< o.o5). candida colonization was found in 15% of the treatment and 60% of the control group, either during or after radiotherapy (p= 0.003). positive cultures for aerobic pathogenic bacteria were observed in 15% percent of the treatment group and 65% of the control group, during or after radiotherapy (p=0.007). As a conclusion this study shows that prophylactic use of pure honey was effective in reducing mucositis resulting from radiotherapy in patients with head and neck cancer.

Khanal (2010) did a study on anti inflammatory properities might limit the severity of radiation induced oral mucositis. The aim of the study was to assess the effect of topical honey on limitation of radiation – induced of mucositis. A single blind randomized, controlled clinical trial was carried out to compare the mucositis limiting of honey with lignocaine. A visual

assessment scale permitted scoring of degrees of oral mucositis and statistical evaluation of the results was performed using the chi square test. The result showed only 1patient in the honey group developed intolerable oral mucositis compared with the control group, indicating the honey was strongly protective (RR= 0.067) against the development of oral mucositis. The proportion of patients with intolerable oral mucositis was lower in the treated group and this was statiscally significant (p=0.000). As a conclusion application of honey topically to the oral mucosa of patients undergoing radiation therapy appears to provide a distinct benefit in limiting the severity of mucositis.

Goyal. M et al (2009) did a study on oral mucositis in morning vs evening irradiated patients. The purpose of the study to evaluate prospectively the severity of acute oral mucositis in head and neck carcinoma patients irradiated in the morning (08.00 – 11.00h) versus late afternoon/ evening (15.00 – 18.00h) . A total of 212 patients of head and neck carcinoma were randomized to morning (08.00- 11.00h) and evening (15.00 – 18.00h) groups. The grades of oral mucosa ulceration were compared in two groups. The results shows the grades of mucositis were marginally higher in the evening irradiated group than in the morning irradiated group 38% versus 26% (P = 0.08). In conclusion the observed incidence of grade III / IV mucositis in morning vs evening irriadiated patients may be because of the existence of circadian rhythm in the cell

cycle of normal mucosa. This knowledge may provide a possibility of treating the patients with decreased toxicity to oral mucosa.

Murphy BA (2009) did a study on mucositis related morbidity and resource utilization in head and neck cancer patients receiving radiation therapy with or without chemotherapy. The objective of this study was to estimate health care resource utilization in head and neck cancer (HNC) patients. This was a prospective, longitudinal, multicenter, noninterventional study of mucositis in patients receiving radiation with or without chemotherapy for HNC. Seventy five patients were enrolled from six centers – fifty (67%) patients received concurrent chemoradiation therapy, 34(45%) received intensity- modulated radiation therapy. Over the course of the treatment, 57(76%) patients reported severe mouth and throat soreness pain and functional impairment because of mouth and throat soreness increased during the course of therapy despite the use of opoid analgesics in 64 (85%) of the patients. As a conclusion this study demonstrates that mucositis related pain and functional impairment is associated with increased use of costly health resources .Effective treatments to reduce the pain and functional impairment of oral mucositis are needed in this patient population.

Rose- ped, Alison M (2002) did a study on complication of radiation therapy for head and neck cancers, the patient perspective, personal interviews were conducted with 33 individuals who had received radiation therapy for head and neck cancers. These individuals described their

treatment experiences and identified the most troublesome and debilitating side effects of radiotherapy. Overall, lethargy and weakness, dry mouth, mouth sores and pain, taste changes and sore throat were the most frequently reported troublesome or debilitating side effects. The single most debilitating side effect was oropharyngeal mucositis that was characterized by patients as sore throat and mouth sores and pain both negatively affected the patients to experience significant weight loss. As a conclusion trends toward more aggressive management of head and neck cancers under the need for new and effective therapies for oropharyngeal mucositis occurring in patients receiving radiotherapy.

Renata Lazari Sandoval (2003) did a study on Oral mucositis is a common complication of some malignancies treatment, causing therapeutic modifications due to patient's debilitation, which often interferes with the prognosis of the disease. Many attempts have been made to find an optimal treatment or preventive method to minimize the severity of oral mucositis. Several studies have shown good results with the use of low-energy laser, with the aim of accelerating the process of wound healing and promoting pain relief. Methods used was Patients (n=18) who developed oral mucositis during chemotherapy and/or radiotherapy were submitted to low-energy laser applications until cessation of symptoms. Mucositis severity was scored by an oral mucositis scale based on clinical features and by an oral toxicity scale from the National Cancer Institute based on the ability to swallow; pain severity was scored by subjects on a visual analogue scale

before and after the applications. In result Immediate pain relief was achieved in 66.6% of the patients after the first application. Based on the functional scale, mucositis grade III (not capable to eat solids) was reduced in 42.85% of the cases. According to the scale based on the clinical features, mucositis grade IV (ulcerative lesions) was reduced in 75% of the patients that presented this grade of mucositis at the beginning of laser therapyas as a conclusionLow-energy laser was well-tolerated and showed beneficial effects on the management of oral mucositis, improving the quality of life during the oncologic treatment.

A.P.Gautham (2012) done a study to evaluated the effect of RK-0202, administered as an oral rinse, on the incidence of severe oral mucositis in patients being treated with of radiation therapy (RT) for tumors of the head and neck. The method used was a prospective, randomized, placebo-controlled, double-blind study that compared the effect of 2 concentrations of RK-0202 with placebo on the incidence of severe oral mucositis at a cumulative RT dose of 60 Gy in 110 subjects. Twenty-seven subjects received RK-0202 5%, 38 received RK-0202 10%, 29 received placebo and 16 received standard of care. Subjects began dosing just prior to RT and continued dosing six times daily throughout RT. Oral mucositis was assessed twice weekly throughout RT by trained oral evaluators.. The result shows the higher dose of RK-0202 (10%) successfully attenuated severe oral mucositis as measured by WHO or NCI-CTC v.3 criteria. The incidence of WHO grade 3 or 4 oral mucositis by a cumulative RT dose of

60 Gy was 35% in the RK-0202 group vs. 54% in the placebo group (p = NS). By 50 Gy the incidences in the RK-0202 and placebo groups were 25% and 54%, respectively (p = 0.053). Similarly, the incidence of NCI grade 3 or 4 oral mucositis by 60 Gy was 64% in the RK-0202 cohort vs. 92% for subjects being treated with placebo (p = 0.005). Subjects treated with RK-0202 required less feeding tube placement compared to placebo recipients (3% vs. 22%, p = 0.037) and less opiate analgesia. The median percent of time on opiates was 6% on RK-0202 vs. 21% on placebo. The overall incidence of serious adverse events was significantly lower in subjects treated with RK-0202 (8% vs. 31%, p = 0.024). In general, there was no benefit noted among subjects who received RK-0202 as a 5% solution. As a conclusion RK-0202 significantly reduced the incidence of severe mucositis in subjects treated with radiotherapy for head and neck cancer and was not associated with significant adverse events.

Trotti et al (2009) performed a systematic review of the literature to better determine the frequency of mucositis in patients undergoing radiation to the head and neck. Thirty-three studies analyzing over 6100 patients were included. The incidence of mucositis in patients undergoing radiation was greater than 90% and was 100% in patients given altered fractionation. The overall incidence of grade 3 and 4 mucositis was 39%, with an incidence of 57% in patients treated with altered fractionation. Although the authors were able to define an incidence rate of mucositis, they also highlighted some of the deficiencies in mucositis research. An additional finding was

that, despite reporting the rates of mucositis, few studies linked mucositis to other outcomes. Specifically, the incidence of pain, dysphagia, and dehydration were rarely reported. More commonly reported (64%) were treatment modifications, though the link to mucositis was rarely noted. As a conclusion Mucositis, xerostomia, and dysphagia are common effects of radiation. With the use of more aggressive treatment regimens the incidence of these effects has increased. One optimistic solution to decrease the incidence of these effects is the development of less toxic agents that are molecularly targeted to the disease without an increase in the intensity of effects of radiation.

Jp Honget'al(2012) did a study on Recombinant human epidermal growth factor treatment of radiation-induced severe oral mucositis in patients with head and neck malignancies. The aim of the study was to evaluated the wound healing effect of human recombinant epidermal growth factor (rhEGF) in head and neck cancer and lymphoma patients with irradiation (with or without combined chemotherapy-induced oral mucositis). Patients at Asan Medical Center who had undergone definitive RT of the head and neck region with or without combined chemotherapy and who had developed severe oral mucositis (higher than the Radiation Therapy Oncology Group grade 3) were treated with topical rhEGF twice daily for 7 days. The evaluation of response with regard to oral mucositis was performed 1 week later. Of the 11 treated patients, three had nasopharyngeal carcinoma, three had carcinoma of the oropharynx, two had

carcinoma of the oral cavity, one had carcinoma of the hypopharynx and two had lymphoma of the head and neck. Six patients received RT only, and five patients received concurrent chemo radiotherapy. All patients showed improvements in their oral mucositis after topical treatment with rhEGF in that the Radiation Therapy Oncology Group grade was significantly decreased (P = 0.0000). As a conclusion this finding suggests that rhEGF is effective and safe for the treatment of radiation-induced mucositis.

3. Studies related to healing of chemo/radiation related oral mucositisWith chlorhexidine mouth wash.

A prospective randomized cross over study was conducted to assess the effectiveness of two oral care protocols differing in the type of mouthwashes. The mouthwashes used for this study were chlorhexidine versus benzydamine. Forty patients undergoing chemotherapy were allocated to receive chlorhexidine first and then benzydamine protocol. Subjects were evaluated in intervals of 3 to 4 days by using WHO grading for mucositis and 10cm visual analogue scale for oral symptom evaluation. The results showed that a significant difference in mean area of oral mucositis grade for subjects received chlorhexidine mouthwash compared to those received benzydamine and revealed that chlorhexidine may be helpful in palliating mucositis symptoms in chemotherapy**(Cheng, K.F.,2003).**

A randomized control trail was conducted to assess the effectiveness of chlorhexidine mouthwash on oral mucositis in patients receiving chemotherapy, total of 130 patients were participated in a clinical trial with pre-post design and single blind system. Subjects were divided into two groups using chlorhexidine mouthwash and placebo as control group. Patients in two groups received daily oral hygiene instructions and were examined daily until the mucositis heal. The results showed that mucositis and its related pain were disappeared after 8 to 14 days and 13 to 14 days respectively(**Setiawan., 2004**).

4.Studies related to comparison of effects of other medications and Chlorhexidine mouth wash in healing chemo/radiation related oral mucositis

Kumar,M., (2008) An experimental study was done to assess the effect of three alcohol-free mouthwashes on radiation-induced oral mucositis in patients with head and neck malignancies. Eighty patients with head and neck malignancies, scheduled to undergo curative radiotherapy, were randomly assigned to receive one of the three alcohol-free test mouthwashes (0.12% chlorhexidine, 1% povidone-iodine, or salt/soda) or a control. The patients were instructed to rinse with 10 ml of the mouthwash, twice a day, for a period of 6 weeks. Mucositis was assessed at baseline and at weekly intervals during radiation therapy, using the World Health Organization criteria for grading of mucositis. Among the 76 patients who

completed the study, patients in the povidone-iodine group had significantly lower mucositis scores when compared to the control group from the first week of radiotherapy. Their scores were also significantly lower when compared to the salt/soda and chlorhexidine groups from the fourth and fifth week, respectively, after radiotherapy. This study shows that use of povidone-iodine mouthwash can reduce the severity and delay the onset of oral mucositis due to antineoplastic radiotherapy.

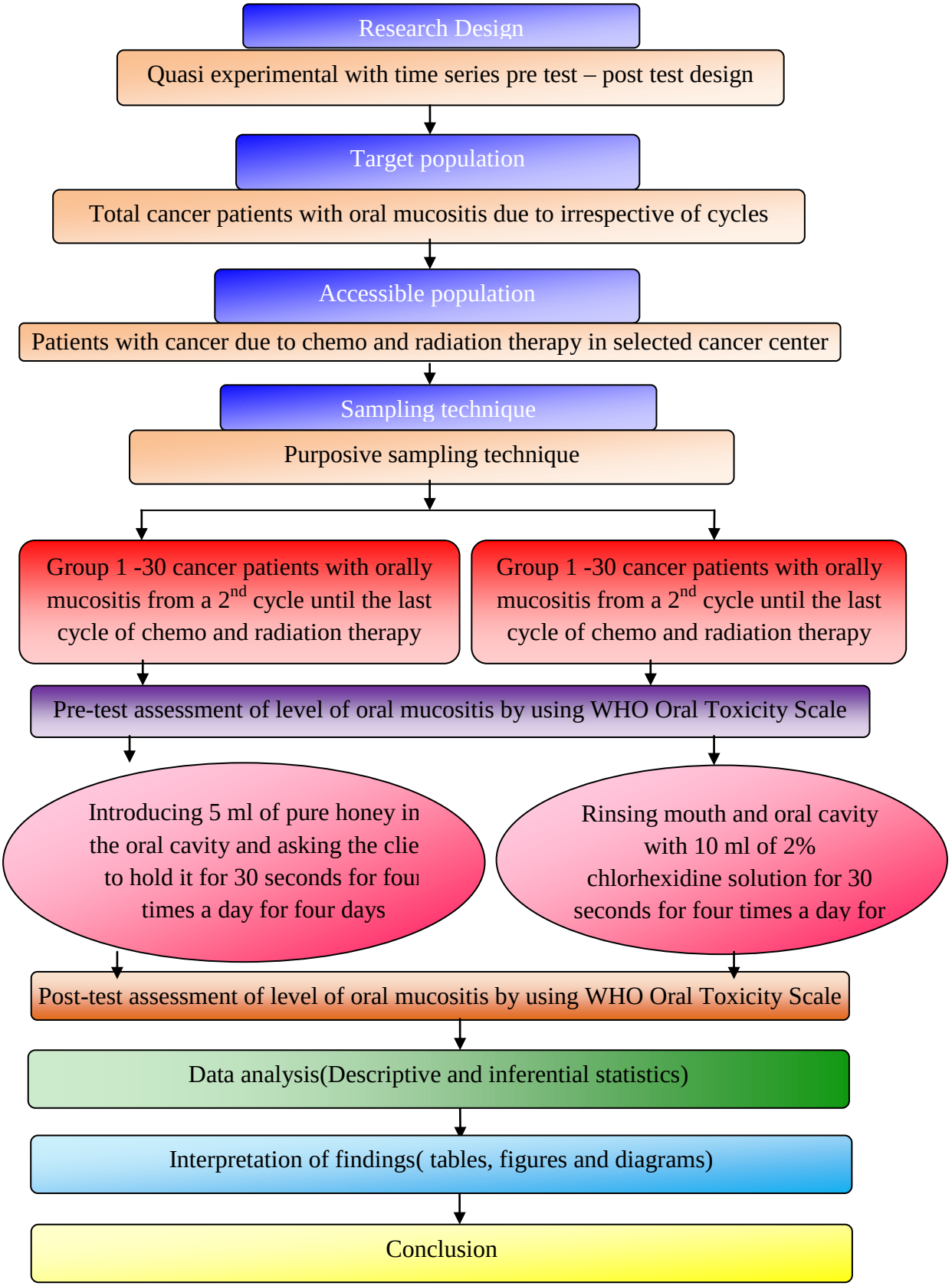
RV.Lalla (2008)A study was conducted toinvestigate whether medicated mouthwashes are effective in the prevention of oral mucositis among patients undergoing chemotherapy. Randomized controlled trials (RCTs) on the use of mouthwashes for the treatment oral mucositis in adult participants undergoing chemotherapy were eligible for inclusion. The severity of mucositis was scored using a World Health Organization (WHO) instrument (or an adaptation of this scale), The instructions for use ranged from a 20 second rinse twice daily to a one minute rinse four times daily. The intervention mouthwashes were salt solution with sodium bicarbonate mouthwash without the active ingredient (chlorhexidine or chamomile), amine-stannous fluoride or water. Two authors independently performed the study selection. Disagreements were resolved through discussion with a third reviewer. Chlorhexidine mouthwash was not found to be more effective than control, the results do not support the use of chlorhexidine mouthwash in the prevention of oral mucositis, and hence the author concluded that the use of salt solution with sodium bicarbonate

rather than chlorhexidine mouthwash for the prevention of oral mucositis associated with chemotherapy is effective.

A. Heydari,(2012)A clinical trial was conducted to evaluate the effectiveness of ice chips to prevent or reduce oral mucositis in patients treated with high doses of Alkeran. The trial included 40 patients with multiple myeloma. Twenty-one patients received ice chips (cryotherapy) 30 minutes prior to treatment and continued to use the ice chips for six hours. Nineteen patients received normal saline instead of ice chips. Severe oral mucositis occurred in 14% of patients treated with ice chips, compared with 74% of patients treated with saline. Individuals treated with ice chips received fewer narcotics and nutrition through a vein than those treated with saline.The researchers concluded that cryotherapy significantly reduces the incidence of severe oral mucositis in patients receiving treatment with high doses of Alkeran. severity P<.01, duration P=.035; cryotherapy severity P<.005, duration P=.003). It was pointed that while ice chips were easy and inexpensive to use, they are drug and schedule dependent and cannot be used with 5-Flurouracil infusions or with chemotherapy with long half lives.

CHAPTER III
METHODOLOGY

FIGURE 2.1
SCHEMATIC REPRESENTATION OF RESEARCH METHODOLOGY



RESEARCH METHODOLOGY

Methodology refers to the technique used to structure a study and to gather and analyze information in a systematic fashion (Polit and Hungler, 2003).This phase of the study includes research approach, research design, setting population, criteria for sample selection, sample size, sampling technique, development and description of tools, reliability, pilot study, data collection procedure and plan for data analysis.

Research approach:

According to Reverso English dictionary"Systematic investigation to establish facts or principles or to collect information on a subjects".

This study was conducted using a quantitative research approach compare the effects of oral honey application and chlorhexidine mouth wash in healing of oral mucositis among cancer patients on chemo and radiation in the selected hospital.

Research design:

According to Denise F. Polit (2011)"The overall plan for addressing a research question, including specifications for enhancing the study's integrity".

The research design adopted for this study was Quasi experimental with time series pre test post test design. It also provides great deal of certainty and efficiency.

Group	Pretest	Intervention	Post test
1[Honey application]Per day x 4 days	O_1	X_1 X_2 X_3 X_4	O_2
2[Chlorhexidine mouth wash] Per day x 4 days	O_1	X_1 X_2 X_3 X_4	O_2

O_1- Assessment of oral mucositis among patients in group 1before the honey application

O_2- Assessment of oral mucositis among patients in group 1 after the honey application.

O_1- Assessment of mucositis among patients in group 2 before the chlorhexidine mouth wash.

O_2- Assessment of mucositis among patients in group 2 after the chlorhexidine mouth wash.

X_1-Administration of 5 ml of honey at 8 am in the morning.

X_2-Administration of 5 ml of honey at 11 am in the morning.

X_3-Administration of 5 ml of honey at 2 pm in the noon.

X_4-Administration of 5 ml of honey at 5 pm in the evening.

Group 1 ×4 days

X_1- Swishing of oral cavity with 10 ml of 0.2% chlorhexidine mouth wash for 30 seconds at 8 am in the morning.

X_2- Swishing of oral cavity with 10 ml of 0.2% chlorhexidine mouth wash for 30 seconds at 11 am in the morning.

X_3- Swishing of oral cavity with 10 ml of 0.2% chlorhexidine mouth wash for 30 seconds at 2 pm in the noon.

X_4- Swishing of oral cavity with 10 ml of 0.2% chlorhexidine mouth wash for 30 seconds at 5 pm in the evening.

Group 2 ×4 days

Variables

According to Denise F. Polit (2011) Variables is defined as "An attribute that varies, that is, takes on different values".

Independent variables

According to Denise F. Polit (2011) Independent variable is defined as "The variable that is believed to cause or influence the dependent variable".

In this study refers to the independent variables is Honey application and Chlorhexidine mouth wash.

Dependent variables

According to Denise F. Polit (2011) Dependent variable is defined as "The variable hypothesized to depend on or be caused by another variable of interest". In this study refers to the independent variables is Oral mucositis

SETTING OF THE STUDY

The study was conducted in International Cancer Center, Neyyoor, Kanyakumari District, which is situated 15 kilometre away from Global College of Nursing, Nataalam, Marthandam. . It is a 100 bedded hospital for oncology patients. Different kind of cancer is treated with radiation and chemotherapy in this hospital. There is a day care centre where patients

come to receive chemotherapy as outpatients basics, also a separate room for delivering radiation therapy for specific fractionated doses as needed for the patients.

POPULATION

According to Denise F. Polit (2011) A Population is defined as "The entire set of individuals or objects having some common characteristics".

The population of this study included all the cancer patients in 2^{nd},3^{rd},or 4^{th} stage of cancer who are on chemo and radiation therapy admitted in International Cancer Center, Neyyoor.

SAMPLE

According to Denise F. Polit (2011) Sample is defined as, "A subset of a population comprising those selected to participate in a study".

The sample for the present study consisted of 60 cancer patients with oral mucositis due to Chemo/Radiation, admitted at International Cancer Center, Neyyoor, at Kanyakumari District. Among them 30 were allotted to Group 1 and 30 were allotted to Group 2.

SAMPLING TECHNIQUE

Suresh K Sharma (2007) Sampling technique is defined as, "The process of selecting a portion of the population to represent to the entire population".

In this study the investigator has intentionally selected 60 cancer patients with oral mucositis due to chemo and radiation therapy from the 2nd cycle until the last cycle of therapies.

Hence the sampling technique is purposive one.

CRITERIA FOR SAMPLE SELECTION

Inclusion criteria:

1) Both male and female cancer patients undergoing chemotherapy / Radiation therapy with oral mucositis
2) Patient from the second cycle of chemotherapy/Radiation therapy.
3) Patients above 18 years of age
4) Chemotherapy/ Radiation therapy patients who manifest oral mucositis
5) Who are present during the study who are willing to participate

Exclusion criteria:

1) Patients in the first cycle of chemotherapy/Radiation therapy
2) Patients who are critically ill.
3) < 18 years
4) Who are not willing to participate in the study
5) Who are not present during the study

DESCRIPTION OF TOOL

According to Denise F.Polit (2011) Instrument or Tool defined as, ”The device used to collect data”.

In this study the tool was developed after the extensive review of literature, internet search and experts advice. It was decided that the assessment of oral mucositis by using WHO oral toxicity scale, could be an appropriate tool to assess the effectiveness of oral mucositis among cancer patient.

The tool developed to collect data in this study consisted into two sections

Section A

This section consisted of the options given for each demographic variables such as age, sex, frequency of mouth wash, personal habits duration of illness, stages of cancer received chemotherapy, received radiation therapy.

Section B

The scale selected appropriately to measure the criteria of Oral mucositis was WHO oral toxicity scale, a standardized scale developed by National Cancer Institution (1999).

The scale consisted of four categories of manifestations which are treated as the basic criteria for the assessment of oral mucositis.

Grade 0- None

Grade1- Soreness erythema

Grade2- Erythema ulcer can eat solids

Grade3- Ulcer liquid diet only

Grade4- Alimentation not possible

CONTENT VALIDITY

According to Denise F. Polit (2011) Content validity defined as "The degree to which the items in an instrument adequately represent the universe of content for the concept being measured".

The content validity was not necessitated since the investigator has used a standardized criterion based measurement scale to assess the oral mucositis.

RELIABILITY

According to Denise F. Polit (2011) Reliability is defined as, "The degree of consistency or dependability with which an instrument measures an attribute".

The reliability was assessed by using test retest method r = 0.89 hence it was highly reliable and the tool was used in this study.

ETHICAL CONSIDERATIONS

An accumulation of values and principles that address questions of what is good or bad in human affairs ethics searches for acting or refaining

from acting for approving conduct for believing or denying something as out.

This study was initiated by obtaining the written approval of dissertation committee of Global College of Nursing.

A written informed consent was obtained from incharge of the cancer centre, Neyyoor to conduct the study.

PILOT STUDY

According to Denise F. Polit (2011) Pilot study is defined as, "A small-scale version or trial run, done in preparation of a major study".

It is a trial rehearsal for the main study. The pilot study was conducted in CSI Medical Mission, Neyyoor for the period of three days. A formal permission was obtained from the Medical Superintend of CSI Medical Mission, Neyyoor.The sample size was six oral mucositis patients and they were selected by purposive sampling technique, three of them were allotted to group 1 and three in group 2. It was established with the patients and a brief introduction about the study was given consent was obtained from each subject .Reassurance was provided that the data collected would be kept confidential. The data relating to demographic variables were collected by observation checklist method. Honey was applied for treatment induced oral mucositis in patient with cancer in group 1 at the Concentration: 5 ml of honey in oral cavity for 30 seconds and then swallowing it for four times a day for group 1 chlorhexidine mouth wash given at the group 2

Concentration: Rinsing of oral cavity with 10 ml of 0.2% chlorhexidine solution for 30 seconds for four times a day for four days.

The data collected were analysed using descriptive and inferential statistics. The result revealed that the honey application had equal effect like chlorhexidine mouth wash in healing oral mucositis due to chemo/Radiation therapy.

PROCEDURE FOR DATA COLLECTION

The investigator selected sixty samples, thirty in group 1 and thirty in group 2. Using the purposive sampling technique. On selection of the study subject self introduction was given and verbal consent was obtained from the subjects and the confidentiality of the response was assured. The demographic data were collected from the samples selected.

A pre test was done in both groups 1 and 2 in which the level of oral mucositis was assessed by using the WHO Oral Toxicity Scale. The researcher then administered 5 ml of honey in oral cavity for 30 seconds and then swallow and for group 2 Swishing of oral cavity with 10 ml of 0.2% chlorhexidine mouth wash solution for 30 seconds was done four times a day for four days.

The investigator assessed the effectiveness of honey application on the treatment induced oral mucositis in group 1 and the effectiveness of chlorhexidine mouth wash on oral mucositis in the group 2 using the same observation checklist and WHO Oral Toxicity Scale.

PLAN FOR DATA ANALYSIS

The collected data were analyzed by using descriptive and inferential statistics .

DESCRIPTIVE:

- Statistics was used to analyse the demographic variables.
- Frequency and percentage distribution of the demographic variables.
- Frequency and percentage distribution of the pre and post test level of oral mucositis among group 1 and group 2.

INFERENTIAL STATISTICS

- Mean and standared deviation was used to assess the pre test and post test level of oral mucositis among patients in the group 1 and group 2.
- Paired t-test was used to compare the pre and post test scores of oral mucositis between group 1 and group 2.

Chi-square test was used to determine the association between the pre interventional level of chemotherapy induced oral mucositis among group I and group II with their selected demographic variables.

Analyzed data were interpreted in tables, diagrams, graphs based on the findings

CHAPTER IV

DATA ANALYSIS AND INTERPRETATION

The purpose of analysis was to reduce the data collected in an intelligible and interpretable form, using different statistical methods such as descriptive and inferential statistical analysis.

According to Polit and Hungler (2005) analysis is the method of organizing, sorting and scrutinizing data in such a way that research question can be answered.

In this study deals with the analysis and interpretation of the collected data from 60 patients with oral mucositis in order to assess the effectiveness of honey application and chlorhexidine mouth wash, by comparing the pre and post test scores among both group 1 and group 2.

The analysis and interpretation of data were based on data collection and the results were computed by using descriptive (mean, frequency, percentage distribution and standared deviation) and inferential ('t'-test and chi-square test) statistics and the results were interpreted in tables, figures and diagrams.

The study findings are presented in sections as follows:

Section: 1 Description of demographic variables of patients with oral mucositis in group 1 and 2.

Section: 2 Assessment of the level of oral mucositis among patient with Cancer due to chemo or radiation therapy in both Group 1 and 2.

Section: 3 Effectiveness of oral honey application on level of oral mucositis. Among patient with cancer due to chemo and radiation therapy.

Section: 4 Effectiveness of chlorhexidine mouth wash on level of oral mucositis. Among patient with cancer due to chemo and radiation therapy.

Section: 5 Association between the pre test level of oral mucositis among patients, with cancer due to chemo and radiation therapy with their selected demographic variables in group 1 and group 2.

SECTION 1

DESCRIPTION OF DEMOGRAPHIC VARIABLES OF PATIENT WITH ORAL MUCOSITIS

Table 1.1: Frequency and percentage distribution of demographic variables in the Group 1 and 2.

Sl no	Demographic variables	Group 1 [Honey application]		Group 2 [Chlorhexidine mouth wash]	
		F	%	F	%
1.	Age(in years)				
	a) 20-29	2	7	5	17
	b) 30-39	6	20	4	13
	c) 40-49	8	27	8	27
	d) 50-59	5	17	10	33
	e) 60-69	9	30	3	10
2.	Sex				
	a) Male	12	40	16	53
	b) Female	18	60	14	47
3.	Frequency of mouth wash				
	a) Once a day	4	13	3	10
	b) Twice a day	9	30	7	23
	c) Every time after eating	17	57	20	67
	d) Others specific	-	-	-	-
4.	Personal habits				
	a) Smoking	8	27	11	37
	b) Alcoholism	14	47	15	50
	c) Betal chewing	8	27	4	13
	d) Others specify	-	-	-	-
5.	Stages of cancer				
	a) 1st stage	0	0	0	0
	b) 2^{nd} stage	12	40	17	57
	c) 3^{rd} stage	10	33	9	30
	d) 4^{th} stage	8	27	4	13

6.	Received chemotherapy per month				
	a) 1-5 times	13	43	16	53
	b) 5-10 times	14	47	10	33
	c) 10-15 times	3	10	4	13
	d) Above 15 times	-	-	-	-
7.	Received radiation therapy per month	8	27	14	47
	a) 1-5 times	15	50	10	33
	b) 5-10 times	5	17	4	13
	c) 10-15 times	2	7	4	13
	d) Above 15 times				
8.	Duration of illness				
	a) Less than 1 year	12	40	14	47
	b) 1-4 years	9	30	6	20
	c) 4-8 years	6	20	7	23
	d) Above 8 years	3	10	3	10

The above tables shows with regard to that Age in years in group 1,2(7%) were in the age group of 20-29 years, 6(20%) were in the age group of 30-39 years,8(27%) were in the age group of 40-49 years,5(17%) were in the age group of 50-59 years,9(30%) were in the age group of 60-69 years where as in the group 2,5(17%) were in the age group of 20-29 years, 4(13%) were in the age group of 30-39 years,8 (27%) were in the age group of 40-49 years,10(33%) were in the age group of 50-59 years,3(10%) were in the age group of 60-69 years.

With regard to the sex in the group 1, 12(40%) were males and 18(60%) were female where as in the group 2, 16(53%) were males and 14(47%) were females.

Regarding frequency of mouth wash in the experimental group 1, 4(13%) of patients taking a mouth wash once a day, 9(30%) of patient taking a mouth wash twice a day, 17(57%) of patient taking mouth wash every time after eating. No one is taking mouth wash specifically. Frequency of mouth wash in the experimental group 2, 3(10%) of patients taking a mouth wash once a day, 7(23%) of patient taking a mouth wash twice a day, 20(67%) of patient taking mouth wash every time after eating. No one is taking mouth wash specifically.

With regard to the personal habits in experimental group 1 8(27%) of patient taking smoking, 14(47%) of the patient taking alcoholism, 8(26%) of the patient taking betal chewing . Whereas in experimental group 2 11(37%) of patient taking smoking, 15(50%) of the patient taking alcoholism, 4(13%) of the patient taking betal chewing.

About the stages of cancer that in experimental group 1 0(0%) of patient in 1^{st} stage, 12(40%) of the patient in 2^{nd} stage, 10(33%) of the patient in 3^{rd} stage, 8(27%) 0f the patient in 4^{th} stage. Whereas in experimental group 2 0(0%) of patient in 1^{st} stage, 17(57%) of the patient in 2^{nd} stage, 9(30%) of the patient in 3^{rd} stage, 4(13%) 0f the patient in 4^{th} stage.

Regarding the received chemotherapy in experimental group 1 13(43%) of patient received chemotherapy 1-5 times, 14(47%) of the patient received chemotherapy 5-10 times, 3(10%) of patient received chemotherapy 10-15 times, 0(0%) of patient received chemotherapy above

15 times. Whereas in experimental group 2 16(53%) of patient received chemotherapy 1-5 times, 10(33%) of the patient received chemotherapy 5-10 times, 4(13%) of patient received chemotherapy 10-15 times, 0(0%) of patient received chemotherapy above 15 times.

With regard to the received radiation therapy in experimental group 1 8(27%) of patient received radiation therapy 1-10 times, 15(50%) of the patient received radiation therapy 10-20 times, 5(17%) of patient received radiation therapy 20- 30times, 2(7%) of patient received radiation therapy above 30 times. Whereas in experimental group 2, 14(47%) of patient received radiation therapy 1-10 times, 10(33%) of the patient received radiation therapy 10-20 times, 4(13%) of patient received radiation therapy 20- 30times, 4(13%) of patient received radiation therapy above 30 times.

Regarding the duration of illness in experimental group 1, 12(40%) of patient in less than 1 year, 9(30%) of the patient in 1-4 years, 6(20%) of the patient in 4-8 years, 3(10%) of the patient in above 8 years. Whereas in experimental group 2, 14(46%) of patient in less than 1 year, 6(20%) of the patient in 1-4 years, 7(23%) of the patient in 4-8 years, 3(10%) of the patient in above 8 years.

Fig 3.1: Percentage distribution of samples according to age in years

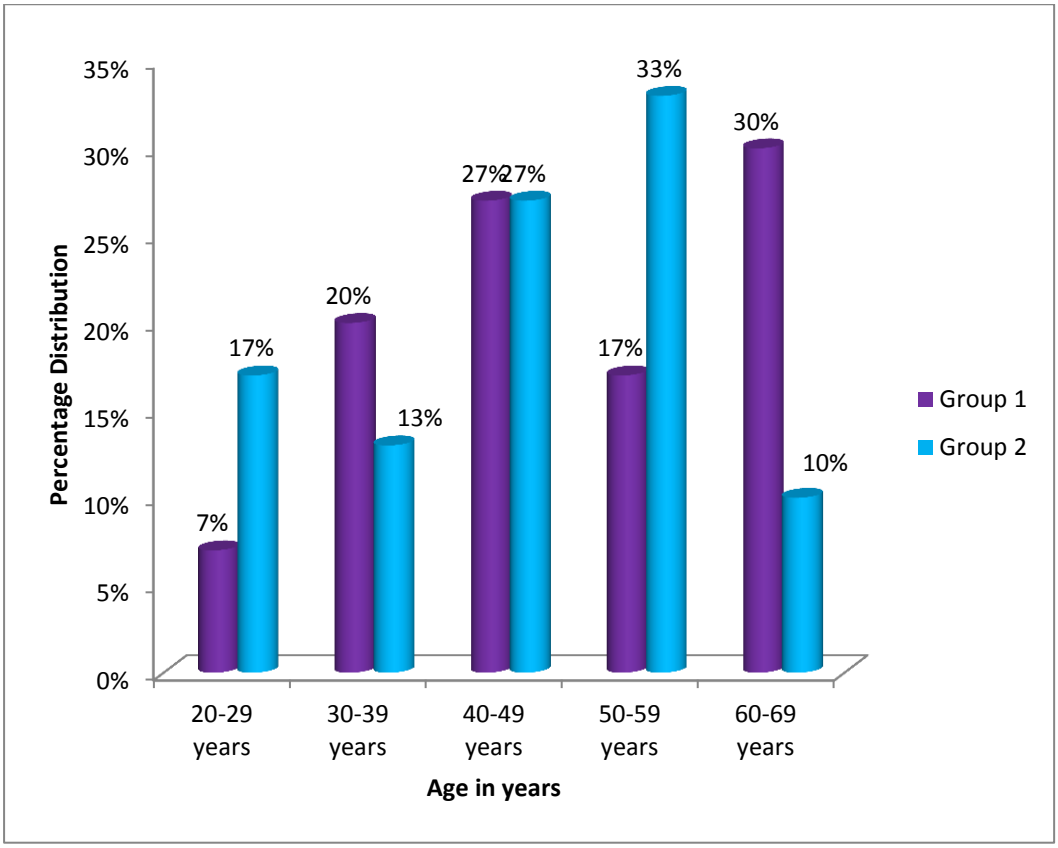


Fig 3.2: Percentage distribution of samples according to gender in years

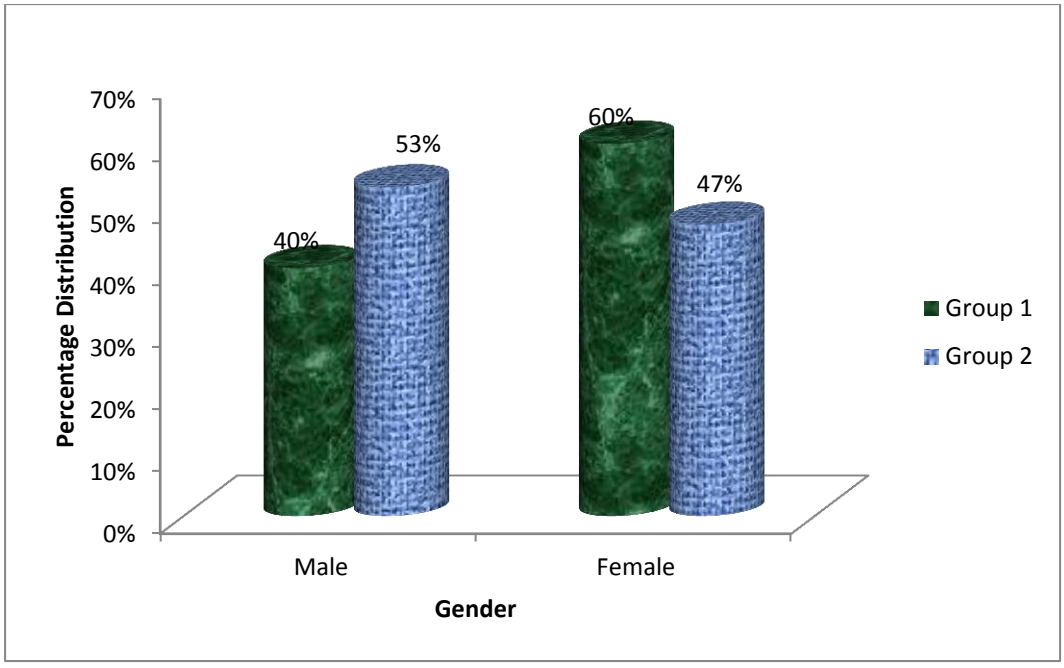


Fig 3.3: Percentage distribution of samples according to frequency of mouth wash

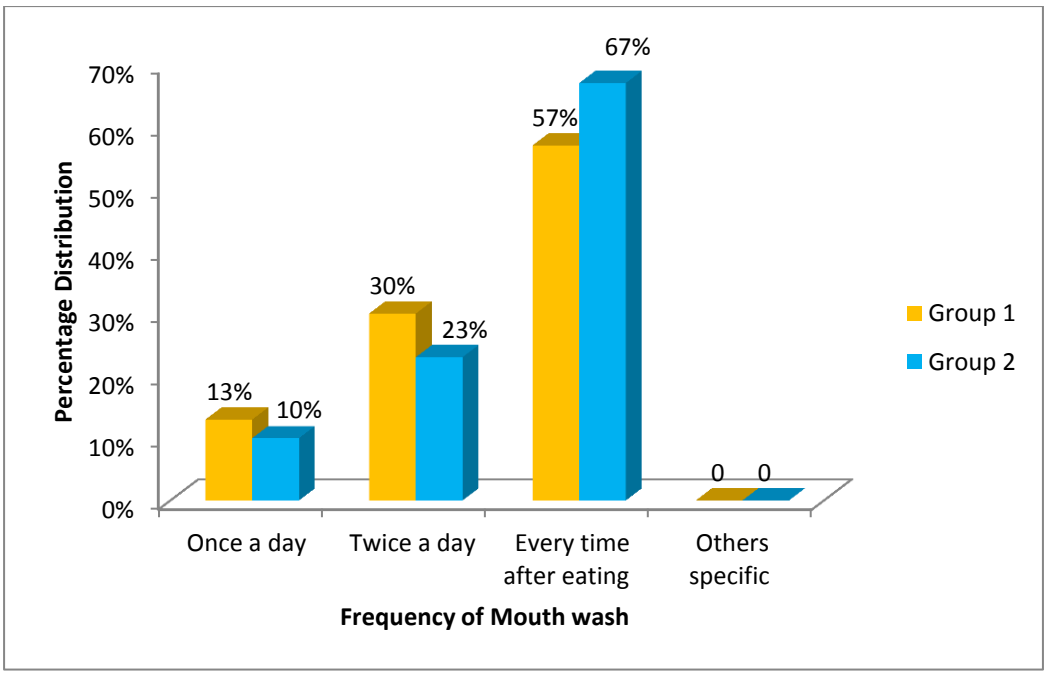


Fig 3.4: Percentage distribution of samples according to personal habits

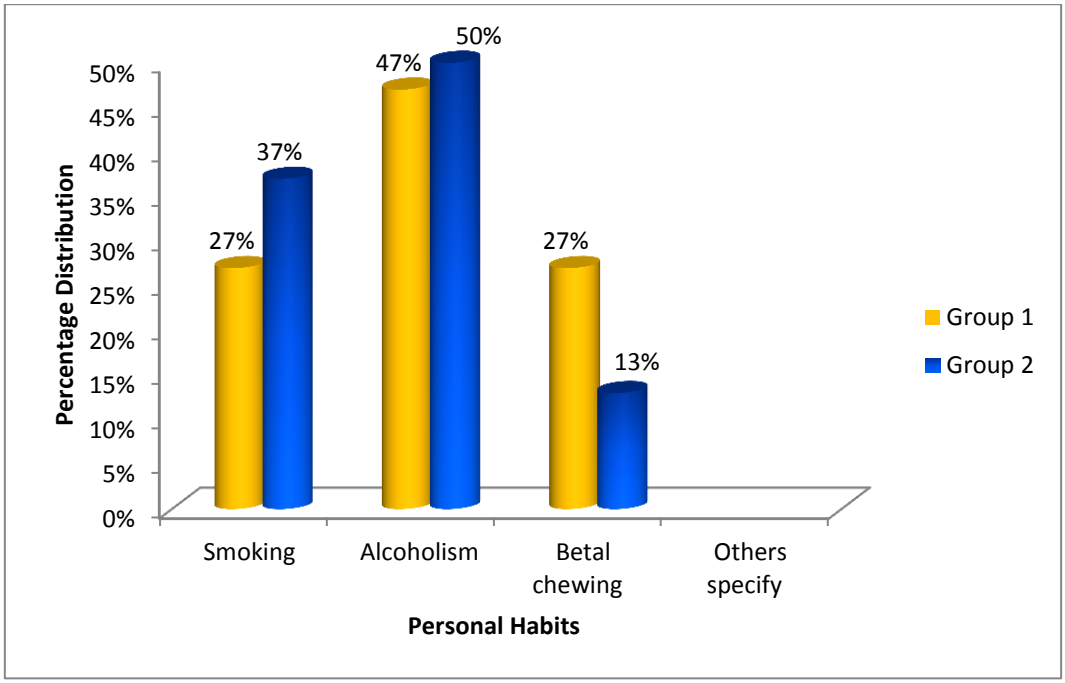


Fig 3.5: Percentage distribution of samples according to stages of cancer

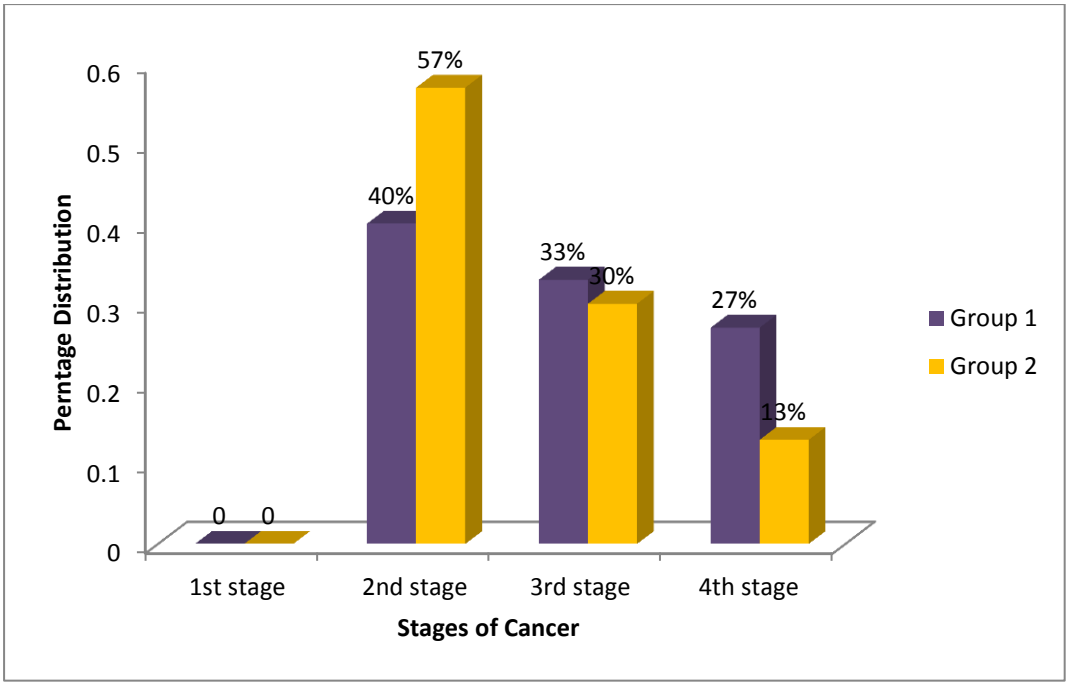


Fig 3.6: Percentage distribution of samples according to received chemotherapy

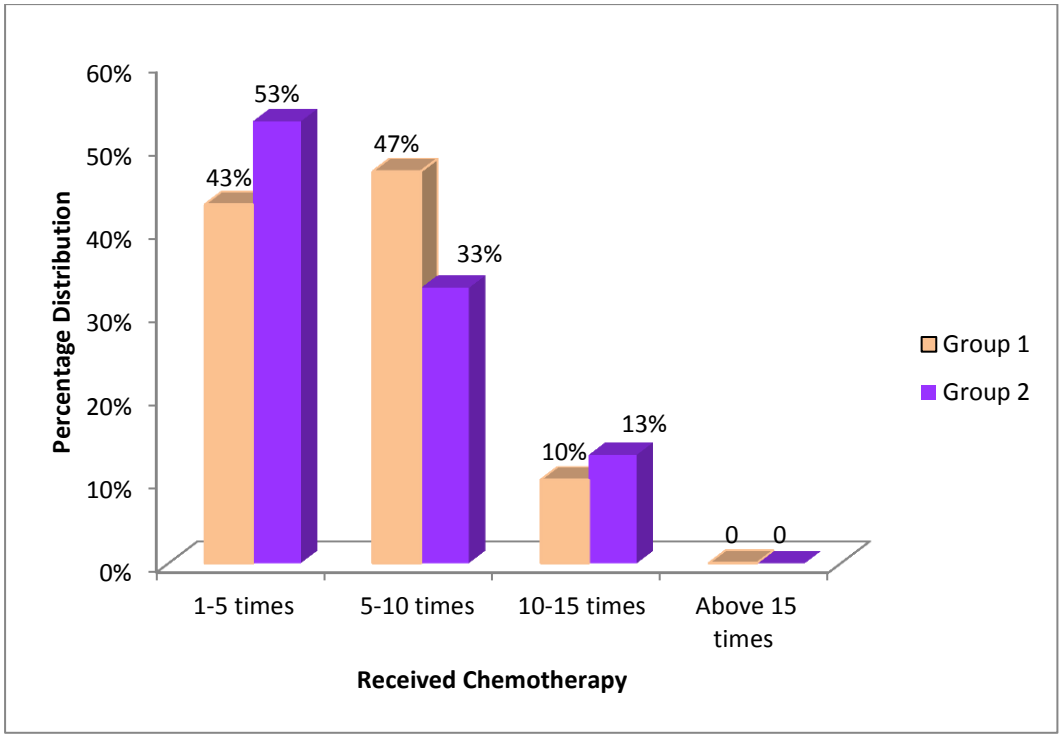


Fig 3.7: Percentage distribution of samples according to received radiation therapy

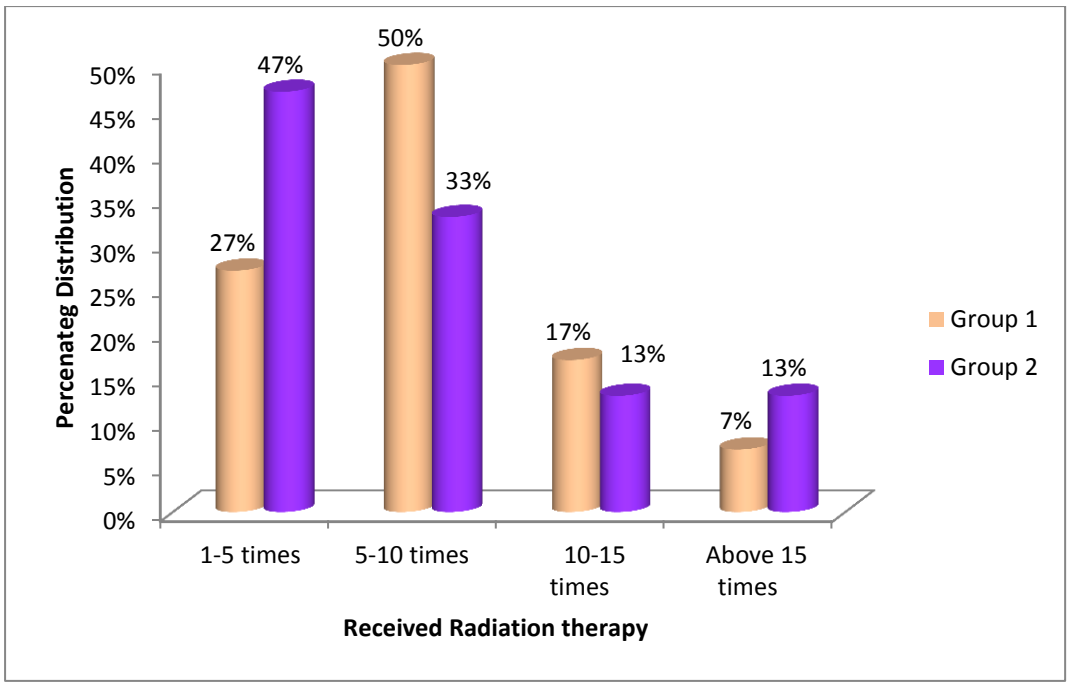
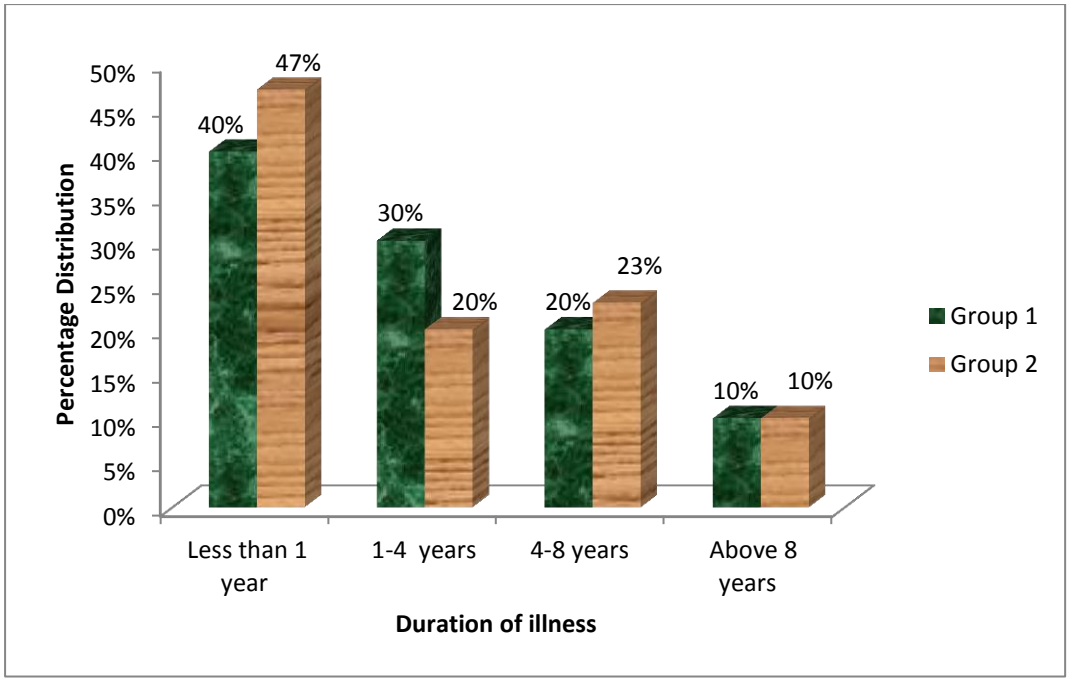


Fig 3.8: Percentage distribution of samples according to duration of illness



SECTION 2

Table 2.1: Frequency, percentage distribution of selected subjects as per their level of oral mucositis in group 1

Sl no	Level of oral mucositis	Group 1			
		Pre test f %		Post test f %	
1	Grade 0	0	0	20	67
2	Grade 1	0	0	10	33
3	Grade 2	0	0	0	0
4	Grade 3	17	57	0	0
5	Grade 4	13	43	0	0

The above table 2.1 shows the level of oral mucositis in the group 1 among patient with cancer.

Out of 30 subjects in the group 1, 17(57%) of them had Grade 3 level oral mucositis, 13(43%) had Grade 4 level of oral mucositis in their pre-test assessment. Whereas in the post-test 20(67%) of them had Grade 0, 10(33%) had Grade 1 level of oral mucositis.

Table 2.2: Frequency, percentage distribution of selected subjects as per their level of oral mucositis in group 2

Sl no	Level of oral mucositis	Group 2			
		Pre test		Post test	
		f	%	f	%
1	Grade 0	0	0	11	37
2	Grade 1	0	0	19	63
3	Grade 2	0	0	0	0
4	Grade 3	20	67	0	0
5	Grade 4	10	33	0	0

The above table 2.2 shows the level of oral mucositis in the group 2 among patient with cancer.

Out of 30 subjects in the group 2, 20(67%) of them had Grade 3 level oral mucositis, 10(33%) had Grade 4 level of oral mucositis in their pre-test assessment. Whereas in the post-test 11(37%) of them had Grade 0, 19(63%) had Grade 1 level of oral mucositis.

Table 3.1: Comparison of pre and post test level of oral mucositis among patient with cancer in group 1

Sl no	Group 1	Mean	SD	MD	't' value
1	Pre test	3.5	0.489	3.2	2.68
2	Post test	0.3	0.447		

*-significant at p< 0.05 level

Table 3.1 reveals that among group 1 the mean pre-test score was 3.5 with standard deviation with 0.489. The mean post-test was 0.3 with standard deviation 0.447. The mean difference was 3.2. The obtained't' value was 2.68, where as the table value was 2.04. It was significant at p< 0.05 level.

It was inferred that oral honey application was highly effective in healing of oral mucositis among clients with cancer.

Fig 3.9: Comparison of pre and post test level of oral mucositis among patient with cancer in group 1

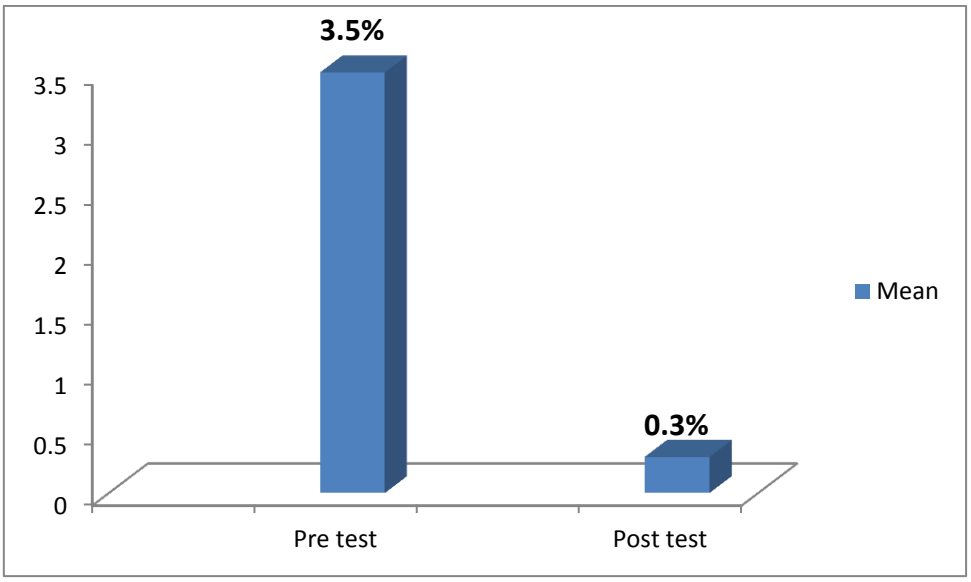


Table 3.2: Comparison of pre and post test level of oral mucositis among patient with cancer in group 2

Sl no	Experimental Group 2	Mean	SD	MD	't' value
1	Pre test	3.6	0.465	3.0	2.65*
2	Post test	0.6	0.474		

*-significant at p< 0.05 level

Table 3.2 reveals that among group 2 the mean pre-test score was 3.6 with standard deviation with 0.465. The mean post-test was 0.6 with standard deviation 0.474. The mean difference was 3.0. The obtained 't' value was 2.65, where as the table value was 2.04. It was significant at p< 0.05 level.

It was inferred that chlorhexidine mouth wash was highly effective in healing oral mucositis among clients with cancer.

Fig 3.10 Comparison of pre and post test level of oral mucositis among patient with cancer in group 2

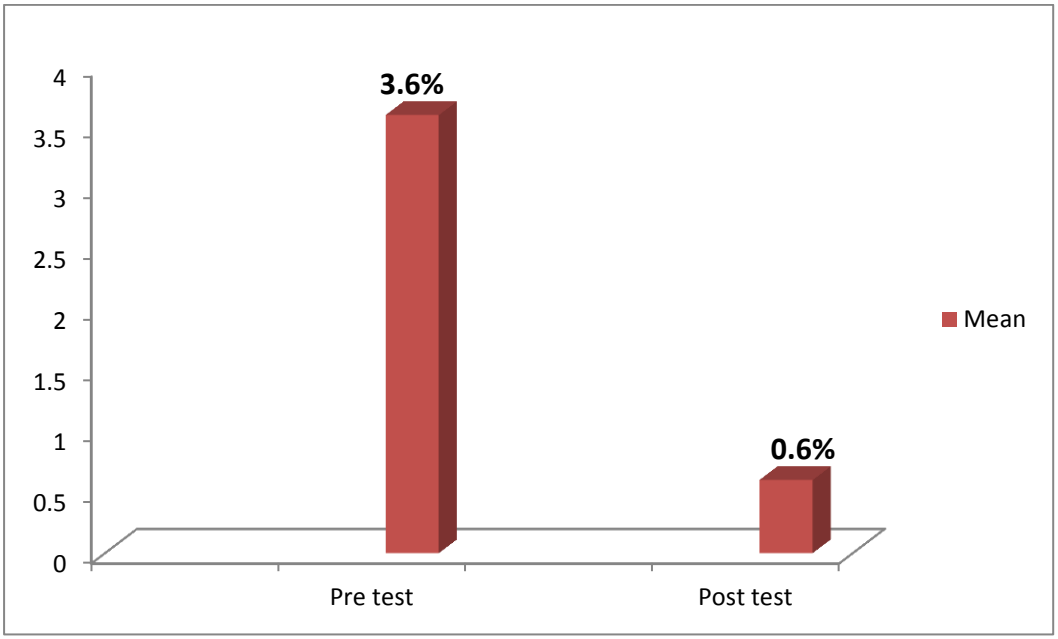


Table 3.3: Comparison of post and post test level of oral mucositis among patient with cancer in group 1 and 2

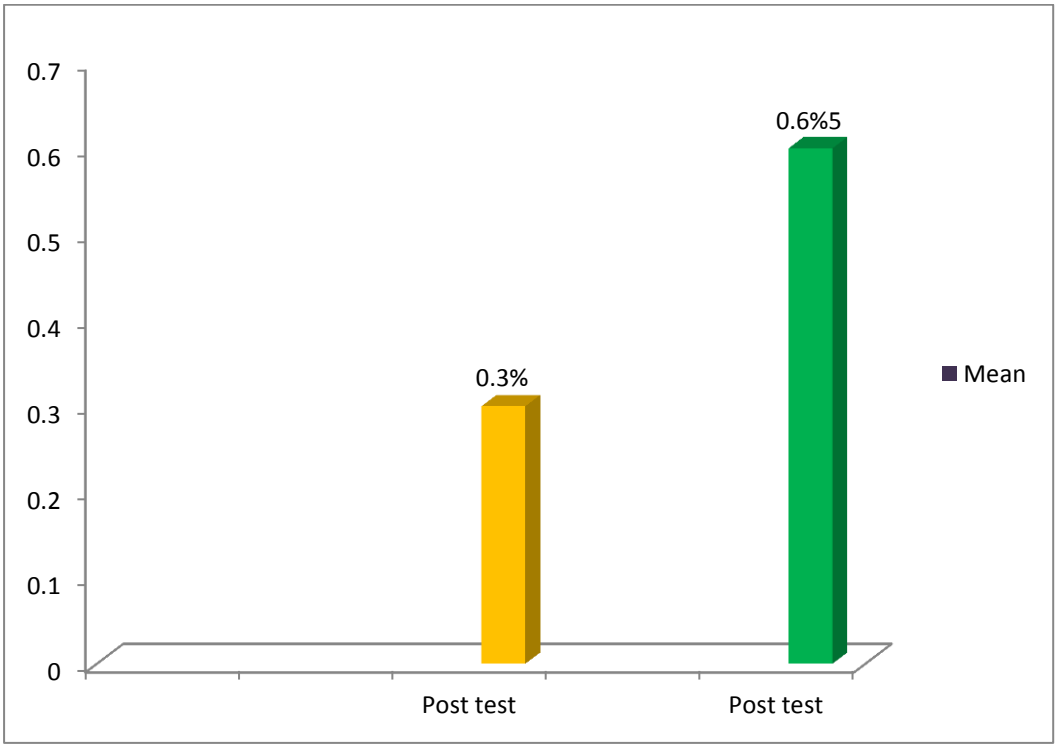
Sl no	Group	Mean	SD	MD	't' value
1	Group 1 (post test)	0.3	0.447	2.1	2.65*
2	Group 2 (post test)	0.6	0.474		

*- significant at p< 0.05 level

Table 3.3 reveals that among group 1 the mean post test score was 0.3with standard deviation with 0.447. In the group 2 the mean post test was 0.63, with standard deviation 0.474. The mean difference was 1.9. The obtained't' value was 4.5, and the table value was (1.6), which was significant at p< 0.05 level.

It was inferred that oral honey application and chlohexidine mouth wash are effective in healing oral mucositis among clients with cancer.

Fig 3.11: Comparison of post and post test level of oral mucositis among patient with cancer in group 1 and 2



SECTION IV

Table 4.1: Association value of pre test level of oral mucositis with selected subjects in group 1 and 2

n=60

Sl No	Demographic variables	Level of oral mucositis										χ^2 Value
		Grade 0		Grade 1		Grade 2		Grade 3		Grade 4		
		f	%	f	%	f	%	f	%	f	%	
1.	Age in years											
	a)18-29	0	0	0	0	0	0	8	13	9	15	
	b) 30-41	0	0	0	0	0	0	10	17	8	13	1.91 df=12
	c)42-53	0	0	0	0	0	0	4	7	8	13	
	d)54-65	0	0	0	0	0	0	5	8	8	13	
2.	Sex											
	a) Male	0	0	0	0	0	0	10	17	17	28	2.43 df=4
	b) Female	0	0	0	0	0	0	19	32	14	23	

3	Frequency of mouth wash											
	a) Once a day	0	0	0	0	0	0	4	7	6	10	
	b) Twice a day	0	0	0	0	0	0	10	17	7	12	1.78
	c) Every time after eating	0	0	0	0	0	0	13	22	20	33	df=12
	d) Any specific	0	0	0	0	0	0	0	0	0	0	
4.	Personal habits											
	a)Smoking	0	0	0	0	0	0	9	15	11	18	
	b)Alcoholism	0	0	0	0	0	0	14	23	18	30	0.08 df=8
	c)Betal chewing	0	0	0	0	0	0	4	7	4	7	
5.	Stages of cancer											
	a)1st stage	0	0	0	0	0	0	0	0	0	0	
	b)2nd stage	0	0	0	0	0	0	15	25	15	25	
	c)3rd stage	0	0	0	0	0	0	9	15	12	20	0.81 df=12
	d)4th stage	0	0	0	0	0	0	3	5	6	10	
6.	Received chemotherapy											
	a)1-5 times	0	0	0	0	0	0	11	18	15	25	
	b)5-10 times	0	0	0	0	0	0	9	15	12	20	
	c)10-15 times	0	0	0	0	0	0	5	8	4	7	0.51 df=12
	d)Above15 times	0	0	0	0	0	0	2	3	2	3	

7.	Received radiation therapy											
	a)1-10 times	0	0	0	0	0	0	10	17	7	12	
	b)10-20 times	0	0	0	0	0	0	6	10	12	20	5.62 df=12
	c)20-30 times	0	0	0	0	0	0	8	13	5	8	
	d)Above 30 times	0	0	0	0	0	0	3	5	9	15	
8.	Durationof illness											
	a)Less than 1 year	0	0	0	0	0	0	4	7	8	13	
	b)1-4 years	0	0	0	0	0	0	14	23	15	25	7.42 df=12
	c)4-8 years	0	0	0	0	0	0	6	10	8	13	
	d)Above 8 years	0	0	0	0	0	0	3	5	2	3	

*- significant at P<0.05 level df = degree of freedom

Table 4.1 indicates the sustentative summary of chi-square analysis, which was used to bring out the association between the level of oral mucositis and their selected demographic variables.

With regard to age, 8(13%) were 18-29 years of age experienced grade 3 level of oral mucositis, and 9(15%) experienced grade 4 level of oral mucositis. 10(17%) were 30-41 years of age experienced grade 3 level of oral mucositis, and 8(13%) experienced grade 4 level of oral mucositis.4(7%) were 42-53 years of age experienced grade 3 level of oral mucositis and 8(13%) experienced grade 4 level of oral mucositis. 5(8%) were 54-65 years of age experienced grade 3 level of oral mucositis, and

8(13%) experienced grade 4 level of oral mucositis . The obtained chi-square value was 1.91 which is statistically not significant at $p < 0.05$ level.

With regard to Gender, among male 10(17%) were experienced grade 3 level of oral mucositis and 17(28%) experienced grade 4 level of oral mucositis. Gender, among female 19(32%) were experienced grade 3 level of oral mucositis and 14(23%) experienced grade 4 level of oral mucositis. The obtained chi-square value was 2.43 which is statistically not significant at $p < 0.05$ level.

With regard to the frequency of mouth wash, among Once a day 4(7%) experienced grade 3 level of oral mucositis and 6(10%) experienced grade 4 level of oral mucositis. Frequency of mouth wash, among Twice a day 10(17%) experienced grade 3 level of oral mucositis and 7(12%) experienced grade 4 level of oral mucositis. Frequency of mouth wash, among Every time after eating 13(22%) experienced grade 3 level of oral mucositis and 20(33%) experienced grade 4 level of oral mucositis. The obtained chi-square value was 1.78, which was statistically not significant at $P<0.05$ level.

With regard to the personal habits, among Smoking 9(15%) experienced grade 3 level of oral mucositis and 11(18%) experienced grade 4 level of oral mucositis. Personal habits among Alcoholism 14(23%) experienced grade 3 level of oral mucositis and 18(30%) experienced grade 4 level of oral mucositis. Personal habits among Betal chewing 4(7%) experienced grade 3 level of oral mucositis and 4(7%) experienced grade 4

level of oral mucositis. The obtained chi-square value was 0.08, which was statistically not significant at P<0.05 level.

With regard to the stages of cancer, among 2nd stage of cancer 15(25%) experienced grade 3 level of oral mucositis and 15(25%) experienced grade 4 level of oral mucositis. Stage of cancer, among 3rd stage of cancer 9(15%) experienced grade 3 level of oral mucositis and 12(20%) experienced grade 4 level of oral mucositis. Stage of cancer, among 4th stage of cancer 3(5%) experienced grade 3 level of oral mucositis and 6(10%) experienced grade 4 level of oral mucositis. The obtained chi-square value was 0.81, which was statistically not significant at P<0.05 level.

With regard to Received chemotherapy, regarding the clients receiving 1-5 times of chemotherapy 11(18%) experienced grade 3 level of oral mucositis and 15(25%) experienced grade 4 level of oral mucositis. Clients receiving 5-10 times of chemotherapy 9(15%) experienced grade 3 level of oral mucositis and 12(20%) experienced grade 4 level of oral mucositis. Clients receiving 10-15 times of chemotherapy 5(8%) experienced grade 3 level of oral mucositis and 4(7%) experienced grade 4 level of oral mucositis. Clients receiving Above 15 times of chemotherapy 2(3%) experienced grade 3 level of oral mucositis and 2(3%) experienced grade 4 level of oral mucositis. The obtained chi-square value was 0.51, which was statistically not significant at P<0.05 level.

With regard to Received radiation therapy, regarding the clients receiving 1-10 times of radiation therapy 10(17%) experienced grade 3 level of oral mucositis and 7(12%) experienced grade 4 level of oral mucositis. Clients receiving 10-20 times of radiation therapy 6(10%) experienced grade 3 level of oral mucositis and 12(20%) experienced grade 4 level of oral mucositis. Clients receiving 20-30 times of radiation therapy 8(13%) experienced grade 3 level of oral mucositis and 5(8%) experienced grade 4 level of oral mucositis. Clients receiving Above 30 times of radiation therapy 3(5%) experienced grade 3 level of oral mucositis and 9(15%) experienced grade 4 level of oral mucositis. The obtained chi-square value was 5.62, which was statistically not significant at $P<0.05$ level.

With regard to the duration of illness, among clients suffering less than 1 year 4(7%) experienced grade 3 level of oral mucositis and 8(13%) experienced grade 4 level of oral mucositis . Clients suffering between 1 – 4 years, 14(23%) were experienced grade 3 level of oral mucositis and 15(25%) experienced grade 4 level of oral mucositis. Clients suffering between 4 – 8 years, 6(10%) were experienced grade 3 level of oral mucositis and 8(13%) experienced grade 4 level of oral mucositis. Clients suffering Above 8 years, 3(5%) were experienced grade 3 level of oral mucositis and 2(3%) experienced grade 4 level of oral mucositis. The obtained chi-square value was 7.42, which was statistically not significant at $P<0.05$ level

CHAPTER V

DISCUSSION

The main aim of the study was to compare the effects of oral honey application and chlorhexidine mouth wash in healing of oral mucositis among cancer patients on chemo and radiation therapy. The study was conducted by using quasi experimental design with time.

Series pre and post test with group 1 and Group 2. The present study was conducted in Kanyakumari Medical Mission CSI- International Cancer Center at Neyyoor. The sampling technique is Purposive Sampling technique was used for this study. The total sample size was 60, among them 30 were in the group 1 and 30 were in the group 2. WHO Oral Toxicity Scale was used for data collection. After data collection, data was organized, tabulated, summarized and analyzed. The study findings were discussed in this chapter with reference to the objectives of the study.

OBJECTIVES

1. To assess the level of oral mucositis due to chemo /radiation therapy in patient with cancer among Groups 1 and 2.
2. To assess the post test level of oral mucositis after oral application of honey for group 1 and chlorhexidine mouth wash for group 2.
3. To assess the effect of oral honey application in healing oral mucositis due to chemo/radiation by comparing the pre and post test scores within group 1 .

4. To assess the effect of chlorhexidine mouth wash in healing oral mucositis due to chemo/radiation by comparing the pre and post test scores within group 1 .
5. To compare the effects of oral honey application and chlorhexidine mouth wash in healing oral mucositis due to chemo/radiation
6. To determine the association between the pretest level of oral mucositis due to chemo/radiation among groups 1 and 2 and their selected demographic variables such as age, gender, frequency of mouth wash, personal habits, duration of illness, stages of cancer, received chemotherapy, received radiation therapy.

The first objective of this study was to assess the level of oral mucositis due to chemo radiation therapy in patient with cancer among Groups 1 and 2.

Out of 30 subjects in the experimental group 1, 17(57%) of them had Grade 3 level oral mucositis, 13(43%) had Grade 4 level of oral mucositis in their pre-test assessment. Whereas in the post-test 20(67%) of them had Grade 0, 10(33%) had Grade 1 level of oral mucositis.

Out of 30 subjects in the experimental group 2, 20(67%) of them had Grade 3 level oral mucositis, 10(33%) had Grade 4 level of oral mucositis in their pre-test assessment. Whereas in the post-test 11(37%) of them had Grade 0, 19(63%) had Grade 1 level of oral mucositis.

Parulekar et al.have estimated that chemotherapy-induced mucositis varies from 40 to 76% in patients treated respectively with standard and high-dose chemotherapy. Nearly all (90% to 97%9,24) patients receiving radiotherapy in the head and neck will develop some degree of mucositis. Of these patients treated with radiotherapy with or without chemotherapy, 34% to 43% will present severe mucositis. As a result, the patients quality oflife is affected, hospital admittance rates are higher, the use of total parenteral nutrition is increased and interruption of treatment is more frequent, all of which compromise tumor control. Mucositis causes 9% to 19% of chemotherapy and radiotherapy interruption.

The second objective of this study was to assess the post test level of oral mucositis after oral application of honey for group 1 and chlorhexidine mouth wash for group 2.

It reveals that among experimental group 1 the mean pre-test score was 3.5 with standard deviation with 0.489. The mean post-test was 0.3 with standard deviation 0.447. The mean difference was 1.11. The obtained‘t’ value was 2.68, where as the table value was 2.04. It was significant at $p< 0.05$ level.

It was inferred that oral honey application was highly effective in healing of oral mucositis among clients with cancer

Rashad UM (2006) did a study on honey as topical prophylaxis against radio chemotherapy induced mucositis in head and neck cancer. The aim

of the study is to evaluate the efficacy of pure natural honey as against radio chemotherapy induced mucositis. The study was done in Assiut university Hospital, Egypt between January 2005 and july 2006. 40 patients diagnosed with head and neck cancer were entered into the trial. Enrolled patients were randomized to either the treatment group, receiving concomitant chemotherapy and radiotherapy plus prior topical application of pure honey, or the control group, receiving concomitant chemotherapy and radiation therapy without honey. Patients were evaluated clinically every week to assess development of radiation mucositis. In the results in the treatment group, no patients developed grade four mecositis and only 3 patients (15%) developed grade three mucositis. In the control group 13 patients (65%) developed grade three or four mucositis ($p< 0.05$). As a conclusion this study shows that prophylactic use of pure natural honey was effective in reducing mucositis resulting from radio chemotherapy in patients with head and neck cancer.

It reveals that among experimental group 2 the mean pre-test score was 3.6 with standard deviation with 0.465. The mean post-test was 0.6 with standard deviation 0.474. The mean difference was 1.11. The obtained 't' value was 2.65, where as the table value was 2.04. It was significant at $p< 0.05$ level.

It was inferred that chlorhexidine mouth wash was highly effective in healing oral mucositis among clients with cancer.

The findings of the study was supported byRV.Lalla (2008) A study was conducted toinvestigate whether medicated mouthwashes are effective in the prevention of oral mucositis among patients undergoing chemotherapy. Randomized controlled trials (RCTs) on the use of mouthwashes for the treatment oral mucositis in adult participants undergoing chemotherapy were eligible for inclusion. The severity of mucositis was scored using a World Health Organization (WHO) instrument (or an adaptation of this scale), The instructions for use ranged from a 20 second rinse twice daily to a one minute rinse four times daily. The intervention mouthwashes were salt solution with sodium bicarbonate mouthwash without the active ingredient (chlorhexidine or chamomile), amine-stannous fluoride or water. Two authors independently performed the study selection. Disagreements were resolved through discussion with a third reviewer. Chlorhexidine mouthwash was not found to be more effective than control, the results do not support the use of chlorhexidine mouthwash in the prevention of oral mucositis, and hence the author concluded that the use of salt solution with sodium bicarbonate rather than chlorhexidine mouthwash for the prevention of oral mucositis associated with chemotherapy is effective.

The third objective of this study to assess the effect of oral honey application in healing oral mucositis due to chemo/radiation by comparing the post test scores within group 1 and group 2.

It reveals that among experimental group 1 the mean post test score was 0.3with standard deviation with 0.447. In the experimental group 2 the mean post test was 0.63, with standard deviation 0.474. The mean difference was 1.9. The obtained‘t’ value was 4.5, and the table value was (1.6), which was significant at $p< 0.05$ level.

It was inferred that oral honey application and chlohexidine mouth wash are effective in healing oral mucositis among clients with cancer.

The effectiveness of commonly used mouthwashes for the prevention and treatment of chemotherapy-induced oral mucositis: a systematic review of daily chlorhexidine mouthwash was often recommended for preventing chemotherapy-induced oral mucositis. Povidone-iodine, NaCl 0.9%, water salt soda solution and chamomile mouthwash were also recommended. However, the effectiveness of these mouthwashes was unclear. A systemic review was conducted to assess the effectiveness of mouthwashes in preventing and treating chemotherapy-induced oral mucositis. Based on study quality, three out of five randomized controlled trials were included in a meta-analysis. The results failed to detect any beneficial effects of chlorhexidine as compared with sterile water, or NaCl 0.9%. The severity of oral mucositis was shown to be reduced by 30% using a povidone-iodine mouthwash as compared with

sterile water in a single randomized controlled trial. These results do not support the use of chlorhexidine mouthwash to prevent and treat oral mucositis**.** (Potting,C., 2006).

The forth objective to determine the association between the pretest level of oral mucositis due to chemo/radiation among groups 1 and 2.

Indicates the sustentative summary of chi-square analysis, which was used to bring out the association between the level of oral mucositis and their selected demographic variables.

With regard to age, 8(13%) were 18-29 years of age experienced grade 3 level of oral mucositis, and 9(15%) experienced grade 4 level of oral mucositis. 10(17%) were 30-41 years of age experienced grade 3 level of oral mucositis, and 8(13%) experienced grade 4 level of oral mucositis .4(7%) were 42-53 years of age experienced grade 3 level of oral mucositis and 8(13%) experienced grade 4 level of oral mucositis. 5(8%) were 54-65 years of age experienced grade 3 level of oral mucositis, and 8(13%) experienced grade 4 level of oral mucositis . The obtained chi-square value was 1.91 which is statistically not significant at $p < 0.05$ level.

With regard to Gender, among male 10(17%) were experienced grade 3 level of oral mucositis and 17(28%) experienced grade 4 level of oral mucositis. Gender, among female 19(32%) were experienced grade 3 level of oral mucositis and 14(23%) experienced grade 4 level of oral

mucositis. The obtained chi-square value was 2.43 which is statistically not significant at $p < 0.05$ level.

With regard to the frequency of mouth wash, among Once a day 4(7%) experienced grade 3 level of oral mucositis and 6(10%) experienced grade 4 level of oral mucositis. Frequency of mouth wash, among Twice a day 10(17%) experienced grade 3 level of oral mucositis and 7(12%) experienced grade 4 level of oral mucositis. Frequency of mouth wash, among Every time after eating 13(22%) experienced grade 3 level of oral mucositis and 20(33%) experienced grade 4 level of oral mucositis. The obtained chi-square value was 1.78, which was statistically not significant at $P<0.05$ level.

With regard to the personal habits, among Smoking 9(15%) experienced grade 3 level of oral mucositis and 11(18%) experienced grade 4 level of oral mucositis. Personal habits among Alcoholism 14(23%) experienced grade 3 level of oral mucositis and 18(30%) experienced grade 4 level of oral mucositis. Personal habits among Betal chewing 4(7%) experienced grade 3 level of oral mucositis and 4(7%) experienced grade 4 level of oral mucositis. The obtained chi-square value was 0.08, which was statistically not significant at $P<0.05$ level.

With regard to the stages of cancer, among 2^{nd}stage of cancer 15(25%) experienced grade 3 level of oral mucositis and 15(25%) experienced grade 4 level of oral mucositis. Stage of cancer, among 3^{rd} stage of cancer 9(15%) experienced grade 3 level of oral mucositis and

12(20%) experienced grade 4 level of oral mucositis. Stage of cancer, among 4th stage of cancer 3(5%) experienced grade 3 level of oral mucositis and 6(10%) experienced grade 4 level of oral mucositis. The obtained chi-square value was 0.81, which was statistically not significant at $P<0.05$ level.

With regard to Received chemotherapy, regarding the clients receiving 1-5 times of chemotherapy 11(18%) experienced grade 3 level of oral mucositis and 15(25%) experienced grade 4 level of oral mucositis. Clients receiving 5-10 times of chemotherapy 9(15%) experienced grade 3 level of oral mucositis and 12(20%) experienced grade 4 level of oral mucositis. Clients receiving 10-15 times of chemotherapy 5(8%) experienced grade 3 level of oral mucositis and 4(7%) experienced grade 4 level of oral mucositis. Clients receiving Above 15 times of chemotherapy 2(3%) experienced grade 3 level of oral mucositis and 2(3%) experienced grade 4 level of oral mucositis. The obtained chi-square value was 0.51, which was statistically not significant at $P<0.05$ level

With regard to Received radiation therapy, regarding the clients receiving 1-10 times of radiation therapy 10(17%) experienced grade 3 level of oral mucositis and 7(12%) experienced grade 4 level of oral mucositis. Clients receiving 10-20 times of radiation therapy 6(10%) experienced grade 3 level of oral mucositis and 12(20%) experienced grade 4 level of oral mucositis. Clients receiving 20-30 times of radiation therapy 8(13%) experienced grade 3 level of oral mucositis and 5(8%) experienced

grade 4 level of oral mucositis. Clients receiving Above 30 times of radiation therapy 3(5%) experienced grade 3 level of oral mucositis and 9(15%) experienced grade 4 level of oral mucositis. The obtained chi-square value was 5.62, which was statistically not significant at $P<0.05$ level.

With regard to the duration of illness, among clients suffering less than 1 year 4(7%) experienced grade 3 level of oral mucositis and 8(13%) experienced grade 4 level of oral mucositis . Clients suffering between 1 – 4 years, 14(23%) were experienced grade 3 level of oral mucositis and 15(25%) experienced grade 4 level of oral mucositis. Clients suffering between 4 – 8 years, 6(10%) were experienced grade 3 level of oral mucositis and 8(13%) experienced grade 4 level of oral mucositis. Clients suffering Above 8 years, 3(5%) were experienced grade 3 level of oral mucositis and 2(3%) experienced grade 4 level of oral mucositis. The obtained chi-square value was 7.42, which was statistically not significant at $P<0.05$ level.

CHAPTER VI

SUMMARY, CONCLUSION AND RECOMMENDATIONS

This chapter deals with summary, conclusion, limitation and recommendation of the study. Further it includes implications for the Nursing Practice, Nursing Education, Nursing Administration and Nursing Research.

Summary of the Study

The aim of the study was to compare the effects of oral honey application and chlorhexidine mouth wash in healing of oral mucositis among cancer patients on chemo and radiation in the selected hospital at Kanyakumari district.

The objectives of the study were

1) To assess the level of oral mucositis due to chemo /radiation therapy in patient with cancer among Groups 1 and 2.
2) To assess the post test level of oral mucositis after oral application of honey for group 1 and chlorhexidine mouth wash for group 2.
3) To assess the effect of oral honey application in healing oral mucositis due to chemo/radiation by comparing the pre and post test scores within group 1.

4) To assess the effect of chlorhexidine mouth wash in healing oral mucositis due to chemo/radiation by comparing the pre and post test scores within group 1.
5) To compare the effects of oral honey application and chlorhexidine mouth wash in healing oral mucositis due to chemo/radiation.
6) To determine the association between the pretest level of oral mucositis due to chemo/radiation among groups 1 and 2 and their selected demographic variables

A quasi experimental with time series pre test post test design was chosen for this study. Purposive sampling technique was used for this study. Subjects were selected based upon the inclusion and exclusion criteria. 60 subjects were selected for the study. Purposively 30 Subjects were assigned to the group 1 and 30 subjects were assigned to the group 2.

The tool used to collect the data consisted of two parts, Part I: consisted of demographic Variables with age, gender, education, occupation, stage of cancer, duration of illness, duration of treatment, modality of treatment and number of radiation cycles. Part II consisted of WHO Oral Toxicity Scale to assess the level of oral mucositis among patients with cancer.

Reliability of the tool was calculated by using test-retest method(r =0.89). Data collection was done for 4 weeks. Samplewere selected based on the inclusion and exclusion criteria. Pre test was done by using demographic variables and WHO oral toxicity scale on day one.

Introducing 5 ml of pure honey into the oral cavity and asking the client to hold it for 30 seconds until it spread over and then swallowing it, thus it is done four times a day group 1 and rinsing mouth and oral cavity with 10 ml of 0.2% chlorhexidine solution for 30 seconds for four times a day in group 2.

After the oral honey application and chlorhexidine mouth wash intervention post test was done. Collected data was analyzed by both descriptive statistics (mean, standard deviation, frequency and percentage) and inferential statistics (dependent and independent‘t’ test, chi-square) and results were calculated.

Major Findings of the Study

With regard to the level of oral mucositis among patients with cancer, most of them are under Grade 3 and Grade 4 level of oral mucositis. On post test assessment it revealed that the subjects showed reduction in level of oral mucositis from Grade 4 to Grade 2 and Grade 3 to Grade 1 level of oral mucositis.

It reveals that among experimental group 1 the mean pre-test score was 3.5 with standard deviation with 0.489. The mean post-test was 0.3 with standard deviation 0.447. The mean difference was 1.11. The obtained‘t’ value was 2.68, where as the table value was 2.04. It was significant at $p< 0.05$ level.

It was inferred that oral honey application was highly effective in healing of oral mucositis among clients with cancer.

It reveals that among experimental group 2 the mean pre-test score was 3.6 with standard deviation with 0.465. The mean post-test was 0.6 with standard deviation 0.474. The mean difference was 1.11. The obtained 't' value was 2.65, where as the table value was 2.04. It was significant at $p< 0.05$ level.

It was inferred that chlorhexidine mouth wash was highly effective in healing oral mucositis among clients with cancer.

With regard to the association between the level of oral mucositis and selected demographic variables in group 1 and group 2. The study findings have revealed that in post test in the group 1 there was a significant association between duration of treatment, where as in the group 2 there was a significant association between oral mucositis and received chemo and radiation therapy.

Conclusion

The main conclusion of the present study is oral honey application and chlorhexidine mouth wash both are effective in reducing oral mucositis among patients with cancer which is denoted by significant level of oral mucositis. After the intervention there had been a significant reduction in level of oral mucositis. The selected subjects became familiar and found themselves comfortable and also expressed satisfaction.

Implication of the Study

Nursing implication includes specific information for Nursing practice, Nursing Education, Nursing Administration and Nursing research. Nursing implication for this study is

Nursing Practice

- Oral honey application and chlorhexidine mouth wash for oral mucositis management can be included as nursing procedure to provide care for patients with cancer with oral mucositis.
- Oral honey application and chlorhexidine mouth wash is considered as experimental study and can be imparted to nursing students to improve skill in providing care and update their knowledge on evidence based practice.
- Regular health education program can be conducted in the oncological units by nursing Personnel to help the patients with cancer in reducing the level of oral mucositis.
- Nurses are in best position to oral honey application and chlorhexidine mouth wash the patients with cancer related oral mucositis in oncological units and in the community.
- Nurses play an important role in primary health care by early detection and prevention of oral mucositis. Oral honey application and chlorhexidine mouth wash can be used as a means of health

promotion on level of oral mucositis among patients with cancer receiving cancer treatments.

Nursing Education

- Nurses could learn the assessment of oral mucositis and given oral honey application and chlorhexidine mouth wash in reducing oral mucositis among patients with cancer as a independent nursing intervention.
- Nursing students should be taught about the importance of oral honey application and chlorhexidine mouth wash thereby they can help patients with cancer to overcome oral mucositis.
- Adequate practical training can be given to the nursing staff and students regarding oral honey application and chlorhexidine mouth wash in reduction of oral mucositis and can be incorporated in nursing curriculum.

Nursing Administration

- The Nurse administrators can initiate oral honey application and chlorhexidine mouth wash to reduce the oral mucositis through developmental programme like in-service education and continuing nursing education programme.
- Nurse administrators can prepare written policies and protocols regarding care of oral mucositis.

Nursing Research

- The nurse researcher can conduct many studies in different experimental study to bring about newer perspective in nursing care.
- The study finding will motivate the initial researchers to conduct the same study on large scale and study will be the reference for the extensive and intensive nursing care.

Recommendations

- A similar study can be replicated on a large sample size.
- A similar study can be conducted in different settings.
- A similar study can be done with other intervention to reduce oral mucositis.

BIBLIOGRAPHY

Book References

1.Basavanthappa, B.T. (2003)., "*Nursing Research*"., 1st ed., new Delhi: Jaypee brothers medical publishers (pvt) Ltd,P.452-455

2.Donald Bissett and Jim Cassidey, (2002).,"*Oxford Handbook Of Oncology*".,1st edition.,p.202-205

Dorothy. et.al, (1995)., "*Fundamentals Of Nursing Research*"., 2nd ed., USA: Jones and Bartlett publication

Frederick O. Stephens (2009) "*Text Book Of Basics Of Oncology*"4th ed.,Springer Heidelberg publishers.p.167-172

5.Fink.M.Regene, (1997)., "*Oncology Nursing Secrets*"., 1st ed., New Delhi: Jaypee Brothers Publishers (pvt).Ltd

6.Gupta, G.S Kappor, (1990)., "*Fundamentals Of Mathematical Statistics*"., New Delhi: Sultan Chand publications

7.Lippincott, (2006); "*Manual Of Nursing Practice*" 8th edition., Lippincott publication

8.Polit and Beck, (2004)., "*Nursing Research Principles And Methods*"., 7th ed., Philadelphia: Lippincott Williams and Wikins company.P.632

9., F. Denise Hungler, (2011)., "*Nursing Research Generating And Assessing Evidence For Nursing Practice*"., 9th ed., Philadelphia: Lippincott Williams and Wikins publication.P.190

10.Park k.(2004) "*Text Book Of Preventive Medicine*". 17th ed. Jabalpur.banarsidas bhanot Publishers;P.1405

11.Shirley E. Otto,(2004)"*Oncology Nursing*"., 4th ed., Missouri: Mosby Publication

12. SundarRao, P.S.S. and Richard, (2004).,"*An Introduction To Biostatistics*"., 3rd ed., New Delhi: Prentice-Hall of India Private Ltd.

13. Suzanne C. Smeltzer, Benda G. Bare. *Textbook of Medical Surgical Nursing*. 9thed. Philadelphia : Lippincott; 2000. p. 276-281.

Journal References

1.Alka Saxena. Cancer chemotherapy and its side effect management. Nursing Journal of India 2006 May ; (5) :109-110

2.Atsushi S etal. Prophylaxis of Mucosal Toxicity by Oral Propantheline and cryotherapy in Children with Malignancies Undergoing Myeloablative Chemo-Radiotherapy.Tohoku Journal of Experimental Medicine 2006; 210(4) :315-20

3. Cheng K.Evaluation of an oral care protocol intervention in the prevention of Chemotherapy-induced oral mucositis in paediatric cancer patients. European Journal of Cancer ;37(16) :2056-2063

4. Karis Kin Fong.Oral mucositis, dysfunction, and distress in patients undergoing cancer therapy. Journal of clinical nursing 2007; (16): 2114-2121

5. RP. Symmols, Treatment- induced mucositis;an old problem with new remidies British Journal of Cancer,1998;77(10):1689-95

6. Serife Karagozogulu. Chemotherapy: the effect of oral cryotherapy on the development of oral mucositis. Journal of clinical Nursing 2005; (14): 754-763.
7. Wolfgang JK, Michael H, Catharina W, Christoph C, Zielinski.Oral Mucositis Complicating Chemotherapy and/or Radiotherapy: Options for Prevention and Treatment.CA-A Cancer Journal for Clinicians 2001; 51:290

Net References

1. Allison Gandey. Mouthwash Prevents Chemotherapy-Induced Oral Mucositis. Medscape Medical News.
Availableat http://www. medscape.com/ viewarticle/ 5458
2. Article Outlines Health Benefits of HoneyIndian ExpressKhanal**.** Oral mucositis-related morbidity and resource utilization in a prospective study of head and neck cancer patients. Available from: URL:http://apitherapy.blogspot.com/2007/01/article-outlines-health-benefits
3. Complications of radiation therapy for head and neck cancers. The patient's perspective. Rose-Ped AM, Bellm LA, Epstein JB, Trotti A, Gwede C, Fuchs HJ. Available From: URL:http:// www.ncbi.nlm.nih.gov /pubmed/12464838
4. Dr Biswa Mohan Biswal is an associate professor in clinical oncology and head of department of nuclear medicine, radiotherapy and

oncology, Medical School, USM Available From: URL:http:// www.honey2010.kk.usm.my

5. Honey as topical prophylaxis against radiochemotherapy-induced mucositis in head and neck cancer.Available From: URL:Http: //www.ncbi.nlm.nih.gov/pubmed?Term="Al Gezawy%20SM
6. Management Of Chemo- And Radiotherapy Induced Oral Mucositis With Low-Energy Laser: Initial Results Of A.C. Camargo Hospital Renata Lazari Sandovall. Available From: URL:Http://www.Scielo.Br/ Pdf/Jaos /V11n4/ A11v11n4.Pdf
7. Nathaniel S T. Chemotherapy-Induced Oral Mucositis. .(Online). Available from http://clinicaltrials.gov/ct2/show/NCT00118339
8. Oral cancer News. Ice chips prevent Mouth sores associated with high dose chemotherapy. (Online). Available from http:// oralcancernews. org/wp/ice-chips-prevent-mouth-sores-associated-with-high-dose chemotherapy
9. Worthington HV, Clarkson JE, Eden OB.Interventions for preventing oral mucositis for patients with cancer receiving treatment (Review). (online). Abstract available at http://www.cochrane.org/ reviews/en/ ab000978.html
10. Vokurka S etal. The comparative effects of povidone-iodine and normal saline mouthwashes on oral mucositis in patients after high-dose chemotherapy and APBSCT--results of a randomized multicentre study.(Online). Abstract Available at http://www./springerlink.com/ content

APPENDIX –I

KANYAKUMARI MEDICAL MISSION
INTERNATIONAL CANCER CENTRE, NEYYOOR

Dr. V.G. SUDHAKARAN MD.
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NEYYOOR - 629 802,
KANYAKUMARI DT,
TAMIL NADU, S. INDIA.

21.03.2014
Date .....

CERTIFICATE

Mr.M.Berlin Rajan, II year M.Sc (N), student of Global College of Nursing, Nattalam, has undergone data collection for his research works in International Cancer Centre, Neyyoor during the period from 18.02.2014 to 17.03.2014 and has been completed his works.

KANYAKUMARI MEDICAL MISSION INTERNATIONAL CANCER CENTRE NEYYOOR - 629 802 KANYAKUMARI DISTRICT TAMIL NADU

Dr.V.G.Sudhakaran, M.D.,DMRT
Head, Radiation Oncology
International Cancer center
Neyyoor - 629 802(T.N)

APPENDIX –II

TOOLS FOR DATA COLLECTION

Section- A: Demographic variables

Sample No: ☐

Date: ……

Demographic data:

1. Age (in years)

a) 20 - 29 ( )

b) 30 - 39 ( )

c) 40 - 49 ( )

d) 50 – 59 ( )

e) 60 – 69 ( )

2. Sex

a) Male ( )

b) Female ( )

3. Frequency of self mouth wash

a) Once a day ( )

b) Twice a day ( )

c) Every time after eating ( )

d) Others-specify ( )

4. Personal habits

a) Smoking ( )

b) Alcoholism ( )

c) Betal chewing ( )

d) Others specify ( )

5. Stages of cancer

a) 1st stage ( )

b) 2nd stage ( )

c) 3rd stage ( )

d) 4th stage ( )

6. Received chemotherapy

a) 1-5 times ( )

b) 5-10 times ( )

c) 10-15 times ( )

d) Above 15 times ( )

7. Received radiation therapy

a) 1-5 times ( )

b) 5-10 times ( )

c) 10-15 times ( )

d) Above 15 times ( )

8. Duration of illness

a) Less than 1 year ( )

b) 1-4 years ( )

c) 4-8 years ( )

d) Above 8 years ( )

Section –B: WHO Oral Toxicity Scale

WHO Oral Toxicity Scale developed by National Cancer Institution (1999) the tool was use to assess the oral mucositis

Grade 0	Grade 1	Grade 2	Grade 3	Grade 4
None	Soreness erythema	Erythema ulcer can eat solids	Ulcer liquid diet only	Alimentation not possible

Section -C : Intervention

Oral honey application:

5 ml of honey in oral cavity for 30 seconds and then swallowing it for four times a day for group 1

- Administration of 5 ml of honey at 8 am in the morning.
- Administration of 5 ml of honey at 11 am in the morning.
- Administration of 5 ml of honey at 2 pm in the noon.
- Administration of 5 ml of honey at 5 pm in the evening.

Chlorhexidine mouth wash:

Rinsing of oral cavity with 10 ml of 0.2% chlorhexidine solution for 30 seconds for four times a day for four days.

- Swishing of oral cavity with 10 ml of 0.2% chlorhexidine mouth wash for 30 seconds at 8 am in the morning.
- Swishing of oral cavity with 10 ml of 0.2% chlorhexidine mouth wash for 30 seconds at 11 am in the morning.
- Swishing of oral cavity with 10 ml of 0.2% chlorhexidine mouth wash for 30 seconds at 2 pm in the noon.
- Swishing of oral cavity with 10 ml of 0.2% chlorhexidine mouth wash for 30 seconds at 5 pm in the evening.